⑫ # EUROPEAN PATENT APPLICATION

㉛ Applicant: **TEXAS RESEARCH, INC.**
**8603 Botts Lane**
San Antonio Texas 78217(US)

㉒ Inventor: **Jensen, Robert Leland**
8603 Botts Lane
San Antonio Texas 78217(US)

㉔ Representative: **McCallum, William Potter et al,**
Cruikshank & Fairweather 19 Royal Exchange Square
Glasgow G1 3AE Scotland(GB)

㊴ **High frequency ventilator.**

㊺ A high frequency ventilator (10) which generates a high frequency pressure wave in a supply (26) of ventilating gas for supporting ventilation in air breathing animals. The high frequency pressure wave causes the ventilating gas to be exchanged and to diffuse through the animal's lungs fast enough to support ventilation without spontaneous breathing on the part of the animal and without the aid of a separate ventilator.

There are means provided for producing a high frequency, variable period, variable amplitude pressure wave in said gas, which is polar relative to the static airway pressure in said animal, to actively force gas into and draw gas out of said animal.

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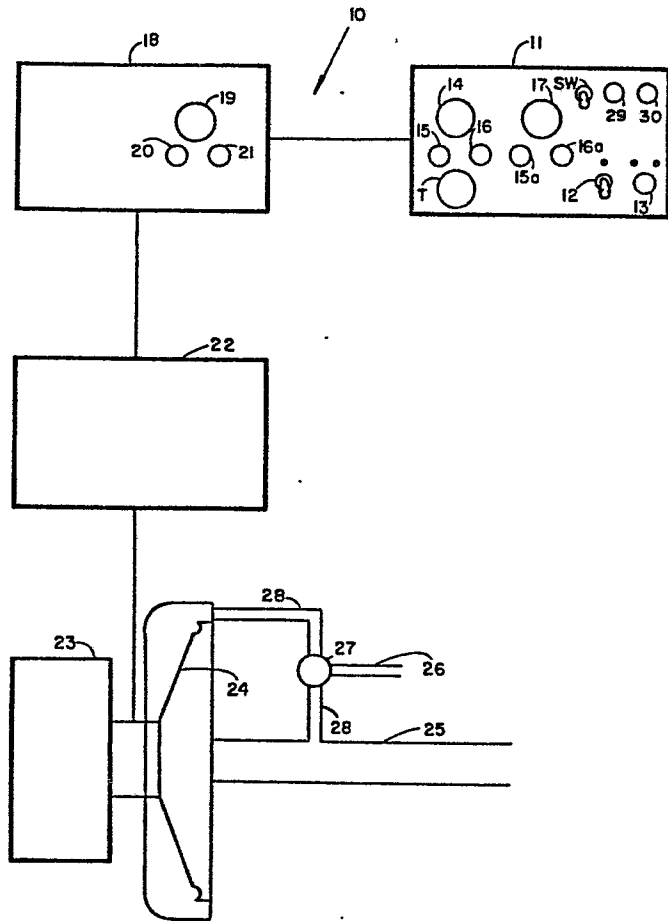
FIG. 1

HIGH FREQUENCY VENTILATOR.

The present invention relates generally to ventilators for supporting ventilation in air breathing animals. More particularly, the present invention relates to high frequency ventilators which operate by oscillating respiratory air supplied to a subject at a frequency above the normal breathing frequency of the subject.

The use of a medical apparatus to facilitate
breathing in mammals is well known in the art. The
apparatus may take the form of a simple oxygen mask or
tent which supplies oxygen at slightly above
atmospheric pressure. Such devices merely assist a
person to breathe and work with the person's lungs.

Ventilators which operate at high frequency
have been suggested in the past. There are two types
of high frequency ventilators known in the art. One
type, as exemplified by U.S. Patent 2,918,917 to
Emerson, employs a reciprocating diaphragm to vibrate
a column of gas supplied to a subject. The vibration
is in addition to the subject's respiration, natural
or artificial, and at a much more rapid rate, for
example, from 100 to more than 1500 vibrations per
minute. The Emerson apparatus is primarily designed
to vibrate the patient's airway and organs associated
therewith, although Emerson also recognized that high
frequency vibration causes the gas to diffuse more
rapidly within the airway and therefore aids the
breathing function. However, the Emerson apparatus is
incapable of supporting the patient's full ventilation
and must be used in conjunction with the patient's
spontaneous breathing or with another apparatus which
produces artificially induced inhalation and exhala-
tion.

The second type of high frequency ventilator
is the jet pulse ventilator as exemplified in U.S.
Patent 4,265,237 to Schwanbom et al. The Schwanbom et
al ventilator produces high frequency high pressure

pulses of air which are capable of fully ventilating a patient. The respiration pulse enters with a pressure of .2 bar (209 cmH$_2$O) to 2.7 bar (2797.2 cmH$_2$O). This pressure is sufficient to expand the lungs during inspiration. Expiration is caused by the natural compliance of the lungs after the jet of air is stopped. Accordingly, it can be seen that Schwanbom et al must rely on the compliance of the lungs in order to fully ventilate the patient. If the lung compliance is low, greater pressure must be used. Schwanbom et al also supply a source of lower pressure gas for spontaneous breathing by the patient. While such jet pulse ventilators are useful for some applications, they are not generally applicable and their use is limited mostly to experimental work.

U.S. Patent 4,155,356 to Venegas discloses a respiration assisting apparatus using high frequency pulses to hold a patient's airway open while the patient is breathing or being ventilated with a volume respirator. As with the Emerson device, Venegas is not capable of fully ventilating a subject and must rely either on the natural respiration cycle or on a volume type respirator to sustain the subject.

It is believed that normal breathing functions of air breathing animals are caused by expansion of the chest cavity. The expansion puts a negative pressure on the outside of the plurality of alveolar sacs in the lungs. The innumerable alveolar sacs receive air from the tidal flow or air movements generated, replenishing the sacs with oxygen

containing gas and removing carbon dioxide containing gas. Normal breathing produces slight pressure differentials on the alveolar sacs to provide the breathing function. The compliance of the sacs causes them to inflate and deflate in response to the pressure changes.

When the chest cavity expands and creates a negative pressure on the outside of the alveolar sacs, it is believed this causes the sacs to inflate and provides movement of air into the alveolar sacs due to the pressure change. In order to exhale, the pressure on the outside of the alveolar sacs is increased by relaxing the chest cavity, causing the elastic alveolar sacs to collapse and allowing expiration.

As far as is known, commercially available prior art ventilators use a high positive air pressure to inflate the lungs like a balloon. If too much pressure is utilized, the compliance or elasticity of the alveolar sacs is reduced. Eventually, the damage will become so extensive that the sacs will no longer function to expel gas and thereby provide oxygen and carbon dioxide exchange.

When a person is hooked up to a ventilator, monitoring of blood gases is used to determine whether or not sufficient oxygen exchange is occurring in the alveolar sacs. When the blood gases deteriorate, present ventilators must correct the problem by increasing the pressure of the gas flowing into the lungs. The increase in pressure affects the compliance and elasticity of the sacs even more and can eventually destroy the lungs. A person essentially becomes addicted to a ventilator and must gradually be weaned from the ventilator.

When there is no lung disease one can use a low pressure with a respirator, because the lungs can breathe on their own to provide the exchange of gases in the alveolar sacs. When there is lung disease present, it may not be possible for the lungs to provide adequate ventilation or gas exchange in the alveolar sacs. This requires some means of facilitating the gas exchange.

The failure of ventilation in conventionally available ventilators generally begins with expiration failures. As mentioned earlier, the conventional method for increasing gas exchange when blood gases deteriorate is to increase the pressure of the gas flowing into the lungs. The lungs can sustain a slight over pressuring for a short period of time and not incur permanent damage. However, continued over pressuring will cause a change in the compliance of the alveolar sacs. A bleb or rupture can occur when the alveolar sac has exceeded its elastic limit. Hemorrhaging may result, which destroys the ability of the sac to effect gas exchange and may cause other complications.

During normal breathing, it is believed that the alveolar sacs gradually deflate until they are no longer providing adequate gas exchange. In order to reinflate the alveolar sacs, an individual must sigh reinflating the alveolar sacs to their full size. Failure to periodically sigh can be fatal because normal breaths allow the alveolar sacs to slowly deflate.

An object of the present invention is to
provide a ventilator which will produce sufficient gas
exchange to sustain full ventilation of a patient
without overpressurizing the patient's lungs.

Another object of the present invention is
to provide a ventilator which does not change the
compliance of the alveolar sacs.

A further object of the present invention is
to provide sufficient volume air exchange combined
with enhanced molecular diffusion of the gases in the
lungs to support full ventilation.

A still further object of the present
invention is to provide mucocilliary clearance to
remove fluid and mucous from the lungs.

Yet another object of the present invention
is to allow the patient to sigh periodically and fully
reinflate the alveolar sacs.

In accordance with the above and other
objects, the present invention is an apparatus for
supporting full ventilation of an air breathing
animal, comprising a source of gas for respirating the
animal and means for supplying a continuous flow of
the gas from the source at a flow rate. A means for
generating a high frequency pressure wave in said
continuous flow of gas is provided and the flow of gas
with the high frequency wave is connected to the lungs
of an animal to be ventilated.

In accordance with other aspects, the inven-
tion includes means for maintaining an elevated static
airway pressure in the animal, and the generating
means comprises a linear motor.

The generating means further comprises means for driving the linear motor with a square wave signal.

Also in accordance with the above objects, the invention is an apparatus for supporting full ventilation in an air breathing animal, comprising a source of respirating gas, means for supplying the respirating gas to an airway of an animal, and means for producing a high frequency pressure wave in the gas, the wave having a positive sloped portion forcing gas into the airway and a negative sloped portion drawing gas out of the airway.

The pressure wave is polarized relative to the static airway pressure in the airway such that the pressure wave has positive and negative amplitude portions relative to the static airway pressure.

The invention may also include means for independently varying the duration of the positive portion of the pressure wave and the negative portion of the pressure wave to vary the inspiration to expiration ratio of the subject.

Also in accordance with the above objects, the invention includes a method for ventilating an air breathing animal, comprising producing a continuous flow of ventilating gas, supplying said continuous flow of gas to an animal to be ventilated, generating a high frequency pressure wave in said flowing gas, said pressure wave being generated with positively and negatively sloped portions to actively force gas into and draw gas out of said animal, and venting gas at a rate equal to the rate of flow of said gas, whereby carbon dioxide from said animal and ventilating gas are exchanged and diffused throughout the airway of said animal and said flowing gas in such a manner that

sufficient ventilating gas reaches the alveolar sacs
of said animal to support full ventilation without
spontaneous breathing by said animal or the use of
additional ventilating devices, and said vented gas
removes carbon dioxide from the animal.

Embodiments of the present invention will now be
described, by way of example, with reference to the
accompanying drawings, in which:-

Figure 1 is a block diagram of a first
embodiment of a high frequency ventilator according to
the present invention;

Figure 2 is a block diagram of a second
embodiment of a high frequency ventilator according to
the present invention;

Figure 3 is a perspective view of a third
embodiment of a high frequency ventilator according to
the present invention;

Figure 4 is a block diagram of the embodiment
of the invention shown in Figure 3;

Figure 5 is a perspective view of a linear
motor used in the present invention;

Figure 6 is an elevational sectional view of
the linear motor taken along line 6-6 of Figure 5;

Figure 7 is a perspective view of an embodi-
ment of the present invention incorporating both a
high frequency ventilator and a volume ventilator;

Figure 8 is a block diagram of the embodiment
of the invention shown in Figure 7;

Figure 9 is a block diagram of a temperature
alarm system for use in the present invention;

Figure 10 is a block diagram of the pneumatic
circuitry of the present invention;

Figure 11 is a schematic circuit diagram showing the electrical circuit used in the embodiments of Figures 1 and 3;

Figure 12 is a schematic circuit for providing two independent sets of operating parameters for producing a two channel output;

Figure 13 is a schematic diagram of the connection of the present invention to a patient;

The preferred embodiment of the invention is a ventilator which uses a signal generator which produces a variable frequency, variable period square wave signal. The signal is directed through an amplifier which has a variable power output. A polar converter converts the square wave to a polar square wave. The amplifier drives a bidirectional linear motor which is connected to a diaphragm which supplies energy to gas in the ventilator. Due to the bidirectional motor, the pressure wave produced has a first portion with a positive slope and a second portion with a negative slope. This causes respirating gas to be both moved into the subject's airway and

withdrawn from the subject's airway. Due to the fact that the square wave is polar, the diaphragm produces a positive and negative pressure in each cycle, relative to the static airway pressure of the subject.

5   Referring to Figure 1 of the drawings, there is shown a schematic view of a high frequency ventilator 10 according to the present invention. The high frequency ventilator 10 includes a signal generator 11. When the toggle switch 12 is turned on,

10   an hour meter T begins running and the signal generator begins operation. Control knob 13 selects one of the two channels which may be alternately selected. A meter 14 indicates the frequency of the signal generated for the selected channel. The control knobs

15   15 and 16 set the frequency for the first and second channels respectively. The control knobs 15a and 16a control the I:E ratio for the respective first and second channels. A meter 17 indicates the period of the square wave signal generated, which coincides with

20   the inspiration to expiration ratio or the I:E ratio. The apparatus is capable of varying the I:E ratio from about 80:20 to 20:80, a range useful in achieving desired waveforms during clinical applications of the machine. The I:E ratio is the duration of the

25   inspiration or positive period of the cycle over the expiration or negative period of the cycle.

          A sigh function is provided by a sigh timer which is controlled by switch SW and control knobs 29 and 30. When the switch SW is on and the control knob

30   13 is set on channel one, the setting of knob 29 provides a predetermined first period of time to elapse during which the system operates on channel one. At the end of the first predetermined period of time, the sigh timer causes the machine to change to

channel two for a second predetermined period of time
as set by control knob 30. The sigh function is set
on channel two by adjusting the frequency, I:E ratio
and power with knobs 16, 16a and 21 respectively. The
sigh function provides a breath of gas of sufficient
volume and duration to enable the alveolar sacs of the
patient to reinflate. Channel two may be set to a
frequency of about 1/2 hz for the sigh and is set at a
high power. This produces a high power, low duration
output which operates essentially in the manner of a
volume ventilator. After the second predetermined
period of time has elapsed, the machine reverts to
operation on channel one for the first predetermined
period of time. The machine continues cycling between
channels one and two when switch SW is in the on
position.

The signal produced by the signal generator
is a variable frequency, variable period square wave.
This signal is directed to an amplifier 18 which is
connected to the signal generator. High frequency
ventilation is considered to begin at about 3 Hz and
extends above this value. The output of the amplifier
18 is shown on the meter 19 and the power gain is
adjusted by control knobs 20 and 21 which control the
first and second channels, respectively. The signal
generated by the amplifier is a variable power,
variable frequency and variable period square wave.

The signal from the amplifier 18 passes to a
polar converter 22 which is connected with the
amplifier. The polar converter 22 serves the dual
function of polarizing the square wave and providing
a connection between the power supply and a linear
motor 23. Linear motor 23 includes a diaphragm 24

which converts mechanical motion to pressure waves in gas. Diaphragm 24 transmits energy to gas in a respirator line 25. Oxygen or compressed gas is added to the system through line 26, a manual two-way needle valve 27 and line 28 to maintain a positive low static pressure on the order of 1 to 15 centimeters of water for the non-diseased lung. A small orifice may be substituted for the valve 27 for economy. For diseased lungs the positive low pressure may be on the order of 7 to 40 centimeters of water. The above pressures have been empirically demonstrated. The valve 27 allows pressure on both sides of the diaphragm to equalize to the mean airway pressure in line 25. A change in mean airway pressure is believed to not effect the waveform because of the equalization. The mean airway pressure (MAP) is the average pressure in the airways on an air breathing animal. Line 25 is connected to an endotracheal tube to supply gas to the patient. A gas exit from line 25 is connected to a line from which gas leaves the system. Appropriate valves and filters are provided as will be discussed hereinafter.

In operation, channel 1 of the signal generator 11 is set to produce a frequency of 3 Hz or greater and channel 2 is set to produce a lower frequency suitable for producing a sigh function. A frequency on the order of about 30 cycles per minute is satisfactory for the sigh function. The desired I:E ratio is set and a source of pressurized gas is attached to line 26. Valve 27 is set such that a flow rate of approximately 5 liters per minute is achieved.

The valves in line 30 are set so that the static
pressure in tube 29 is relatively low yet sufficient
to hold the lungs of the subject open. A static
pressure of about 10 cm of water, for example, has
been found to be satisfactory for this purpose in a
non-diseased lung. The system is operated in this
condition to fully respirate the subject.

During the operation of channel 1,
respirating gas is supplied at a rate of 5 liters per
minute into line 25 and gases from line 25 exit into
outlet line 30 at the same rate. However, because the
concentraton of pure respirating gas in line 25 is
greater than the concentraton of gas contaminated with
carbon dioxide from the subject in tube 29 the pure
respirating gas is diffused through tube 29 into the
subject's lungs. The diffusion acts with a volume
exchange effect produced by the bidirectional drive of
motor 23 to cause gas exchange in the lungs. Although
the mechanism for causing complete gas exchange is not
completely understood, it is believed to be a
combination of molecular diffusion, asympathetic
vibrations of the lung tissue and volume exchange.

It is believed that molecular diffusion is
greatly responsible for the gas exchange. This
diffusion is enhanced by the vibrational energy added
through diaphragm 24 to the point where much of the
respirating gas reaches the subject's lungs and
replaces the carbon dioxide therein. This gas
exchange can be more clearly envisioned by viewing the
source of gas from line 26, as supplying, for example,
oxygenated air which produces an oxygen gradient
throughout tube 29 with a higher partial pressure of

oxygen existing at the outlet of line 28 than in the
rest of the system. The subject's lungs can be viewed
as a source of carbon dioxide which produces a CO_2
gradient throughout tube 29. The partial pressure of
the CO_2 is greater in the lungs than in the rest of
the system. What the ventilator of the present inven-
tion does is to promote the diffusion of these gases
throughout the tube 29, line 25 and lungs of the
subject to such an extent that a large portion of the
oxygen reaches the alveolar sacs of the patient. It
should also be understood that the static pressure
produced by valves 30 is also present to hold the air
passages open thereby ensuring that diffusion can take
place. This is to be clearly contrasted with the
presently known volume ventilators which use high
pressure gas to actually inflate the subject's lungs
to produce only a volume exchange whereby oxygenated
gas is forced under pressure into the lungs to expand
the lungs during inspiration and the compliance of the
lungs forces the carbon dioxide out during expiration.
These known ventilators produce a volume exchange of
gas analogous to the normal breathing function.

The asympathetic vibrations of the subject's
lungs appear to promote mixing of the gases deep in
the lungs and therefore also enhance gas exchange.
These vibrations also appear to aid in moving gases
into and out of the lungs.

The volume exchange effect caused by the
present invention is due to the motor 23 which causes
movement of diaphragm 24 in both directions thereby
giving the resultant pressure wave positive and
negative sloped portions. The positive sloped portion
forces respirating gas into the subject's airway

causing an instantaneous rise in pressure, while the negatively sloped portion actively draws gases out of the airway causing an instantaneous decrease in pressure. This type of gas exchange is to be contrasted with known high frequency jet ventilators which only force gas into the lungs and rely on the compliance of the lungs to push gas back out. In other words, jet ventilators produce pressure waves which only have a positive slope. If it were not for the natural phenomena occurring apart from the jet ventilator, the pressure in the subject's lungs could rise indefinitely, whereas the present invention forces the pressure in the lungs to return to a lower level by actively drawing gases back out.

As discussed above, the signal driving motor 23 is a polar square wave. Ideally, the pressure wave produced in line 25 should also be square in shape. However, this pressure wave would not have a perfect square shape as it emerges from the end of tube 29 in the subject's lungs. The deviation of shape is due to the fluid flow characteristics of the line 25 and tube 29 and compressibility of the gases. In actuality, electrical and pressure waveforms are not perfect in shape. Accordingly, applicant's waveforms, which are characterized as square waves, exhibit for each cycle a relatively rapid rise, a relatively horizontal portion, a relatively rapid decline and a relatively horizontal portion. This is distinguished from high frequency sine waves oscillatory ventilators such as the Emerson patent which constitute part of the prior art. Such sine wave oscillators have been used experimentally but have not been comercially developed as far as known. High frequency jet ventilators exhibit a sawtooth pressure wave, namely a relatively rapid rise, a relatively gradual decline to a value greater than static airway pressure.

the subject, the pressure wave is polar; that is, has both a pos-
itive portion and a negative portion relative to the static
airway pressure in the patient. In this manner, the pulse ampli-
tude does not affect the mean airway pressure except to the ex-
tent produced by a difference in pulse width of the positive and
negative portions of the pulses. Thus, the mean airway pressure
is held at approximately the static pressure set by the valves in
line 30. Each electrical pulse and hence each pressure pulse has
a positive going portion and a negative going portion. Due to
the connection of line 28 of Figure 1, the positive and negative
going portions of the pressure pulse are relative to the static
airway pressure and thus the static airway pressure is equal to
the mean airway pressure.

As long as these positive and negative going portions are
kept within reasonable limits, there is no danger of overpres-
surizing the lungs of the subject. It has been found that a peak
to peak amplitude can be used as a greater static airway pressure
is used. For severely damages lungs, it may be necessary to use
a static pressure as high as 40 cm H_2O. Care should be taken
to be sure that the instantaneous pressure caused by the system
in the lungs does not reach a level low enough to cause lung col-
lapse.

The pressure wave may vary between 5 cm H_2O and 15 cm
H_2O. That is, on the forward stroke of motor 40, the pressure
in the subject's lungs is raised by 10 cm H_2O by forcing gas
into the lungs. On the rearward stroke of motor 40, the pressure
wave is forced to fall from 15 cm H_2O to 5 cm H_2O thereby
drawing gas out of the lungs. At the same time, the pressure
wave is polar relative to the

10 cm H$_2$O static pressure level produced by setting
the values in line 30. Thus, the mean airway pressure
is maintained at approximately 10 cm H$_2$O. The peak to
peak amplitude (power) of the pressure wave can be
varied without affecting the subject's mean airway
pressure. Likewise, the subject's mean airway
pressure can be set independently of the pressure wave
amplitude by adjusting the static pressure of the
ventilation to the desired mean pressure value.

As should be clear from the foregoing
example, the flow of gas into line 26 should be main-
tained at a constant rate since this flow provides the
source of fresh respirating gas and also acts with the
valves in line 30 to maintain the static pressure.

Channel two of the ventilator is set to have
a much lower frequency and a much higher positive
amplitude. When the control switches to channel two,
the low frequency, high amplitude movement of the
diaphragm 24 creates a volume displacement of air into
the patient's lungs to produce a sigh effect. The
characteristics of a volume movement sufficient to
produce a proper sigh effect are well known in the art
and shall not be discussed in detail. It should be
understood, however, that the sigh function is
independent of the high frequency ventilation function.

The second channel is also useful for
providing a second high frequency signal which can be
alternated with the first high frequency signal.
Different high frequencies may be beneficial to
produce different results. For example, one frequency
may be found to be beneficial for the removal of
mucous while a second frequency may produce more
efficient air exchange. Accordingly, by providing the

ventilator with the ability to automatically switch
between two such frequencies both desired results
could be achieved most efficiently.

The electrical circuitry of the ventilator
will now be discussed in detail with reference to
Figure 11, which shows the ventilator with only one
signal generating channel for simplicity.

In Figure 11, a positive DC voltage is shown
applied to the circuit at point 400. A zener diode
and resistor at point 401 reduce the voltage to 15V.
The signal generator section begins at point 402.
Milliammeter 14'' measures the current flowing to the
emitter of unijunction transistor 405. Variable
resistor 403 is adjusted to cause milliammeter 14'' to
indicate the frequency of the signal. Variable
resistor 404 is adjusted to limit the maximum frequency
of the circuit. Potentiometer 15'' allows the operator
to select any frequency between the minimum and the
maximum. Variable resistor 406 is adjusted to bleed
the emitter leakage current of unijunction transistor
405 which prevents capacitor 407 from being charged
except through potentiometer 15''.

As capacitor 407 is charged, the voltage at
the emitter of unijunction transistor 405 rises until
it reaches a fixed proportion of the differential
between base 1 and base 2 of the unijunction transistor
405 at which time it conducts which discharges
capacitor 407 and causes diode 408 to become forward
biased. The signal at the cathode of diode 408 is a
sawtooth wave typical of an astable unijunction
relaxation oscillator and its frequency is variable
through potentiometer 15''.

As diode 408 becomes forward biased due to the negative re-
sistance effect of unijunction transistor 405, it causes transis-
tor 409 to turn off which in turn causes transistor 411 to turn
off. As the base of transistor 409 becomes positive again, it
begins to conduct and transistor 411 turns on after a period of
time determined by potentiometer 15a''. Capacitor 413 drives
transistor 411 into saturation and it remains on until
unijunction transistor 405 again conducts which provides the pos-
itive portion of the square wave. Diodes 410 and 412 add to the
stability of the circuit by providing a base bias voltage differ-
ential to transistor 411 and feedback to the emitter of .
unijunction transistor 405. Variable resistors 414, 415 and 416
with milliammeter 17'' and potentiometer 15a'' comprise the means
whereby the square wave signal is made a variable period square
wave and of indicating its condition of variability as percent
inspiration on milliammeter 17''. When the resistance of
potentiometer 15a'' is at the minimum, the current through
milliammeter 17'' is at the maximum indicating a high inspiration
percent and the charging time of capacitor 413 is at the maximum.
Variable resistor 415 is a shunt for milliammeter 17'' which al-
lows it to be calibrated to indicate the exact percent of in-
spiration of the invention. Variable resistor 414 sets the maxi-
mum inspiration percentage and variable resistor 416 allows cali-
bration of potentiometer 15a''.

Zener diodes 417 and 418 condition the variable frequency
variable period square wave to one of constant amplitude. With-
out them, the positive amplitude of the square wave varies with
the duty cycle. The zener diode and resistor at point 419 reduce
the voltage to the amplifier section to 5V. Transistors 420,
421, 422 and 423 comprise a means whereby the low power signal at
the base of transistor 420 is amplified.

Transistors 452, 453, 454 and 455 comprise the driving tran-
sistors of the polar converter which apply a bipolar signal to
coil 120''' of the linear motor which produces the pressure
variations in the gas in the ventilator. When transistors 452
and 455 are on while transistors 453 and 454 are off, current
flows through coil 120''' in one direction. Transistors 452 and
453 are used in a switching mode and are either biased off or
driven into saturation. Transistors 454 and 455 are used in the
transient regions and are biased off but the extent to which they
are turned on is determined by potentiometer 20''.

When transistor 423 is on, transistor 425 is on and transis-
tor 426 is off thereby biasing transistor 454 off. Transistor
427 is on, transistor 428 is off, transistor 429 is on and tran-
sistor 431 is off thereby biasing transistor 453 off. Simulta-
neously, transistor 430 is on, transistor 433 is off, transistor
434 is off and transistor 435 is biased on to the degree allowed
by the current flowing through potentiometer 20''. Transistor
455 is thereby biased on relative to the position of
potentiometer 20''.

When transistor 423 is off, transistor 425
is off and transistor 426 is biased on to the degree
allowed by potentiometer 20'' and consequently
transistor 454 is biased on proportionally to the
setting of potentiometer 20''. Transistor 427 is off,
transistor 428 is on, transistor 429 is off and
transistor 431 is on thereby biasing transistor 453
on. Simultaneously, transistor 430 is off which
biases transistor 452 off. Transistor 432 is off,
transistor 433 is on, transistor 434 is on and
transistor 435 is off which biases transistor 455 off.

Milliammeter 19'' indicates the relative
percent of power applied to coil 120''' and is
calibrated by variable resistor 424.

The remaining circuitry of Figure 11 is to
prevent mechanical contact between moving and
stationary masses. A mirror 127' is mounted so that
it moves with the coil 120'''. An infrared light
emitting diode 129' is directed at the mirror 127'.
Mounted next to the diode 129' is an infrared
transistor 130'. As the line of sight distance
changes between diode 129' and transistor 130' due to
the movement of the mirror 127', the voltage at the
base of transistor 438 varies. Resistors 436 and 437
provide a voltage divider with an effective variable
resistance through transistor 130'. Transistor 438
amplifies and inverts the signal at the collector of
transistor 130'. Transistor 440 is driven by the
square wave signal present at the anode of zener diode
418 which is amplified by transistor 441. Therefore,
at the anode of silicon controlled rectifier 443,

there is an opposite signal to that at the anode of silicon controlled rectifier 446.

As the current at the base of transistor 438 increases, so does the current at the base of transistor 439. As transistor 439 conducts more, transistor 445 tends to conduct less. Simultaneously, transistor 442 tends to conduct more. Variable resistor 444 determines the current through the emitter of transistor 442 necessary to turn on silicon controlled rectifier 443. The polarity of the coil 120''' is maintained in phase with the signal at zener diode 418 to cause the anode of SCR 443 to be positive when the current at the base of transistor 438 is increasing due to the movement of coil 120'''. When SCR 443 is turned on, it turns on transistor 448 which turns off transistor 451 which reduces the amount of current available to coil 120''' by shunting it through resistor 449 thereby limiting the travel of coil 120'''. When the signal at zener diode 418 reverses, the voltage at the anode of SCR 443 falls below its minimum conduction limits which turns it off and consequently transistor 448 goes off and transistor 451 turns back on allowing full power to the coil 120'''. When transistor 451 is off, light emitting diode 19''' is on and it is protected by zener diode 450.

As the current at the base of transistor 438 decreases, transistor 439 tends to conduct less causing a greater current at the base of transistor 445. Variable resistor 447 controls the point at

which SCR 446 turns on. Being in phase, as transistor 445 turns on, the voltage at the anode of SCR 446 is positive and its operation is similar to SCR 443.

Figure 12 is an electronic schematic diagram showing a timer for use in circuit 11 which produces two independent operating channels for the present invention and automatically switches back and forth between them. In Figure 12, a DC voltage is applied at point 464. For the purposes of this disclosure, the circuit represented in Figure 11 is changed by removing potentiometer 15'' and connecting points 456 and 457 to points 456' and 457' respectively, of Figure 12. Additionally, potentiometers 15a'' and 20'' as shown in Figure 11 are removed and points 458, 459, 460, 461, 462 and 463 are connected to points 458', 459', 460', 461', 462' and 463' respectively of Figure 12.

When switch 13'' is open, relay 467's contacts remain in their normally closed position. Potentiometer 15''' therefore controls frequency, potentiometer 15a'' controls the period of inspiration or duty cycle and indication of it; and potentiometer 20''' controls the power. When switch 13'' is closed, relay 467 is energized which causes potentiometers 15''', 16a'' and 21'' to control frequency, percent inspiration and power respectively, thereby giving a second set of independent operating parameters.

Operationally, when switch 13'' is open, the machine
is said to be operating on "channel one". When switch
13'' is closed, the machine is said to be operating on
"channel two".

Automatic switching between channels one and
two is accomplished by leaving switch 13'' open and
closing switch SW''. Current then flows through the
normally closed contacts of relays 469 and 470.
Potentiometer 29'' controls the time that capacitor
472 takes to charge. When the emitter voltage of
unijunction transistor 473 reaches a fixed porportion
of the voltage between its base 1 and base 2 leads, it
will conduct sending a pulse to the gate of SCR 474
which turns it on. Relay 470 is energized which
interrupts current to this "CHANNEL 1 DURATION"
circuit. Relay 467 is also energized which causes
switching to channel 2 as described above. This first
preset period of time set by potentiometer 29'' is
adjustable by the operator.

Current is also now applied to the "CHANNEL
2 DURATION" circuit begining at point 476.
Potentiometer 30'' controls the time that capacitor
477 takes to charge. When the emitter voltage of
unijunction transistor 478 reaches a fixed proportion
of the voltage between its base 1 and base 2 leads, it
will conduct sending a pulse to the gate of SCR 479
which turns it on which in turn charges capacitor 480
and energizes relay 469 which interrupts the current
to SCR 474 which in turn de-energizes relays 469, 470
and 467 which resets the entire circuit. This second

preset period of time set by potentiometer 30'' is adjustable by the operator. The machine will continue to switch back and forth between channel 1 and channel 2 until SW'' is opened or switch 13'' is closed. Diodes 475 and 466 isolate the circuit functions.

Referring to Figures 5 and 6 there is shown a linear motor 23' for use in a ventilator according to any of the embodiments of the present invention. The linear motor 23' includes a pressure chamber 100 at the upper end thereof. The pressure chamber 100 is connected with one side of a diaphragm 101 and piston member 102. The diaphragm 101 is connected to piston member 102 by retaining ring piston flange 103 through a plurality of screws, 104 and 105 being shown.

Linear motor 23' includes a housing member 106 having cooling fins 106' and a flange 107. The flange 107 is connected to flange 108 by a plurality of screws 109. The diaphragm 101 is clamped between the flanges 107 and 108 and as shown in Figure 6 includes a raised portion to allow for its movement.

The flange 108 is connected to an outlet plate 110 by a plurality of screws 111 opposed to screws 109. O-ring 112 provides a seal between the flange 108 and the outlet plate 110. The diaphragm 101 is made of flexible rubber material and provides a seal between the flange 107 and flange 108. An L-shaped coupling 113 is connected to the outlet plate 110 and is in turn connected to the line 114 which is connected to the line 25'.

A top plate 115 is connected to the housing
106 by a plurality of screws 116. A magnet 117 is
mounted between the top plate 115 and the back plate
118. A plurality of screws or bolts 119 connect the
back plate 118 to the top plate 115 to clamp magnet
117 therebetween.

A coil form 120 is connected by a plurality
of screws 121 to the piston member 102. The coil form
120 constitutes a moving mass.

Spiders or radial limiters 122 and 123 are
glued to the housing 106 and the moving mass 120 and
allow axial movement while preventing radial movement.

A tension spring 124 is connected to the end
125 of the cylindrical coil from 120 by connector
means 126. A mirror 127 is mounted on the coil form
end 125. A position sensor means 128 is provded with
a LED light 129 and an infrared transistor 130. As
the coil form 120 moves up and down so does the mirror
127 and the distance of the mirror 127 from the
infrared transistor 130 is detected. This designates
the position of the piston member 102 and diaphragm
101 at all times. A lead 131 is connected with the
position sensor means 128 for conveying power thereto
and a signal therefrom.

The tension spring 124 is connected at its
upper end 124' to the upper end of the pole piece 142
by connector pin 142'. The spring 124 extends through
central bore 132 extending through the pole piece 142.
A plurality of bores 133, 134, 135 and 136 also extend
all the way through the pole piece 142. As shown in

Figures 5 and 6, the position sensor means 128 extends
through bore 135 and is connected thereto by screw
means 137. The tension of spring 124 equals the
weight of the moving mass of the coil form 120 and
everything mounted thereon at the mid point which
provides a weightless effect at that point.
Electrical leads 138 and 139 connect to a terminal
block 140 attached by screw 141. The terminal leads
138 and 139 are then connected to the coil or winding
120''. As will be apparent the upper end 120' of the
coil form extends through the space between the pole
piece 142 and the top plate 115 to allow up and down
reciprocating motion of the coil form.

The pressure chamber 100 is connected to a
cap means 143 by a plurality of screws 144, 145, 146
and 147 which are in turn connected to the back plate
118. O-rings 148 and 149 seal the pressure chamber
100 with the cap member 143 and the pole piece 142.
The diaphragm 101 and piston member 102 and coil
member 120 convert mechanical motion to pressure waves
in the gas. The larger the pressure chamber 100 the
better so that there won't be substantial modulation
of the pressure wave.

The current in the coil 120'' moves in two
directions by reversing the current which causes the
reciprocating motion of the linear motor.

Another embodiment of the invention is shown
in Figure 2. The high frequency ventilator 10a in
Figure 2 includes a first system A and a second
duplicate system B. A signal generator 50 produces a

square wave which is frequency dependent on the
setting of potentiometer control 51 for channel one or
potentiometer control 52 for channel two. The
frequency of the channel selected is displayed on
digital meter 53. The period of each horizontal
segment of the square wave generated is dependent upon
the setting of control knobs 54 and 55 for the first
and second channels, respectively, and the positive
horizontal segment of the square waves is displayed on
digital meter 56. The control knobs 54 and 55 allow
the inspiration to expiration ratio (I:E) to be varied
according to the needs of a patient.

The sigh function is provided by a sigh
timer which is activated by switch SW' and control
knobs 29'' and 30''. The operation is the same as the
sigh timer for the ventilator 10 except for ventilator
10a it controls the switching between both the first
and second channels of systems A and the third and
fourth channels of system B.

The square wave signal from the first signal
generator 50 is directed to amplifier 57 which
provides a power gain according to the setting of
control knobs 58 and 59 for the first and second
channels, respectively. The percent of available
power is displayed on digital meter 60. The first
amplifier 57 also includes a polar converter which
converts the square waves to polar square waves.

The polar square waves drive the linear
motor 61 in both directions. As the diaphragm is
driven back and forth, it creates a positive and
negative pressure on the gas side of diaphragm 62.

The movement of the diaphragm converts the energy of
the electrical input to the linear motor to an energy
wave in the gas.

At certain frequencies, the gas molecules
are diffused into one another at the molecular level
at greatly increased rates, as compared to the tidal
flow associated with normal breathing. As discussed
above, this phenomenon is apparently due to the energy
added to the gas.

The apparatus also includes a second system
B which has a signal generator 50a whose operation is
identical to the first signal generator 50. The
second signal generator 50a includes potentiometer
controls 51a and 52a which control the frequency of
channels three and four, respectively. The frequency
is displayed on digital meter 53a. The period of the
horizontal segment of the square waves for the third
and fourth channels is dependent on the setting of
control knobs 54a and 55a, respectively. Digital
meter 56a displays the period of each positive hori-
zontal segment of the square waves. As with the first
signal generator 50, generator 50a allows the
inspiration to expiration ratio (I:E) to be varied
according to need.

The square wave signal from generator 50a is
directed to a second amplifier 57a to provide a power
gain for channels three and four, as controlled by the
setting of control knobs 58a and 59a, respectively.
The percent of available power is displayed on digital
meter 60a. The second amplifier 57a includes a polar
converter which converts the square waves from the

signal generator 50a to polar square waves. Amplifier
57a is connected to a linear motor 61a which includes
a diaphragm 62a.

Both sides of diaphragm 62 are connected by
a tubular connector 63 and valve 63'. Similarly, both
sides of diaphragm 62a are connected by tubular
connector 63a and valve 63a'. This provides an
alternating positive and negative pressure to the
ventilator line 65 and equalizes pressure on both
sides of the diaphragms to mean airway pressure in
ventilator line 65.

In operation, assuming the valve 64 is fully
opened and the valve 64a is fully closed, the gas in
the respiratory system, between the diaphragm 62 and
the endotracheal tube 66 is being acted on by the
diaphragm 62 as indicated on digital meters 53, 56 and
60. Compressed air at a pressure as disclosed for
ventilator 10 is supplied through a valve 67 and
oxygen is provided through valve 68 to the line 69
which is connected to a ventilator line 65. The
setting of valves 67 and 68 determine the oxygen
concentration of the gas. The rate of flow thorugh
the system is indicated by the flow meter 70 in line
69.

The humidity of the gas is increased by
humidity generator 71 which is controlled by control
knob 72. The humidity is sensed by a humidity sensor
73 and the humidity is indicated on digital meter 74.

The gas in the ventilator is heated by a
heater 75 which is controlled by control knob 76. The
temperature of the gas in the ventilator is sensed by

the temperature sensor 77 and the temperature is
displayed on the digital meter 78. An alarm is
provided to go off when the temperature is not within
certain limits as set by control knob 79. A control
knob 80 sets an alarm for the humidity level. The
mean airway pressure is indicated by the mean airway
pressure gauge 81 which is equipped with a high and
low alarm. Gas is discharged from the system through
exhaust tube 82.

The signal generator 50, amplifier 57
comprise a first signal generator means which along
with the linear motor 61, diaphragm 62 and valve 64
comprise the first system A. The signal generator
50a, amplifier 57a comprise a second signal generator
means which along with the linear motor 61a, diaphragm
62a and valve 64a comprise the second system B. Each
system can be operated on two separate channels which
are independently set. One channel may be set to
certain parameters and then the operator is also able
to return to the parameters of the other channel at
any time.

As discussed above, a reason for having two
channels per system is to provide a "sigh" function,
which is a deep breath necessary to reinflate the
alveolar sacs, several times per hour. An advantage
of having two redundant systems is to provide
reliability during critical applications. Another
advantage of the dual system is that a high frequency
wave can be superimposed on a low frequency wave.
This will facilitate mucocilliary clearance which is

known to be enhanced by a single high frequency wave.
Actually, the main benefit derived by a high frequency
wave on a low frequency is to introduce physicians to
the benefits of high frequency ventilation slowly.
The low frequency wave can be operated as a conven-
tional volume ventilator if the physician is not
familiar with total high frequency ventilation. After
the merits of high frequency ventilation become more
generally accepted, the use of the low frequency can
be discontinued. The valves 64 and 64a allow any
combination of superimposed waves within the limits of
the individual systems.

Referring to Figure 3 of the drawings, there
is shown a perspective view of a high frequency
ventilator 10'. The high frequency ventilator 10'
includes a signal generator 11' such as shown in
Figures 1, 10 and 11. When the toggle switch 12' is
moved to the on position, power is supplied to the
signal generator 11' as shown in Figure 4. LED
indicator light 12' indicates when the system is on.
Toggle switch 13' selects one of two channels which
may be alternately selected. Digital readout 14'
indicates the frequency as a signal generated for the
selected channel. The control knobs 15' and 16' set
the frequency for the respective first and second
channels. The control knobs 15a' and 16a' set the
period for the respective first and second channels to
control the I:E ratio for the respective first and
second chanels. The digital meter 17' shows the
inspiration to expiration ratio or the I:E ratio.

Channel 1 on the apparatus is selected by moving the toggle switch 13' to the "1" position which will light up the yellow LED's 12a', 15a'', 15'', and 20'' above the appropriate control for adjusting channel 1 operation. Similarly channel 2 may be selected by switching the channel selector toggle switch 13' to the "2" position which will light up the yellow LED's 13b', 16'', 16a'' and 21'' above the appropriate control for adjusting channel 2 operation.

The percent inspiration can be increased by clockwise rotation of the control knobs 15a' and 16a'. Clockwise rotation of the channel 1 control knob 15a' will lengthen the amount of time the ventilator spends on the positive side of the high frequency stroke in channel 1. Similarly, clockwise rotation of the channel 2 control knob 16a' will lengthen the amount of time the ventilator spends on the positive side of the high frequency stroke in channel 2. The LED indicators 15a'' and 16'' above the appropriate controls for the control knobs 15 and 16 indicate the channel which is being activated.

The output of the amplifier is shown on digital meter 19' and the power gain is adjusted by control knobs 20' and 21'. LED indicators 20'' and 21'' above the appropriate control knobs 20' and 21' light up to show which channel is being used. An excessive power LED 19'' lights when the safe power is exceeded. Clockwise rotation of the channel 1 power control knob 20' will increase the amount of power

applied to the high frequency driver shown in Figures
5 and 6. Similarly, clockwise rotation of the channel
2 increase control knob 21' will increase the amount
of power applied to the high frequency driver.
Turning the channel 1 control knob 15' clockwise will
increase the ventilator breath rate if the channel
selector is in the "1" position. Similarly turning
the channel 2 control knob 16' clockwise will increase
the ventilator breath rate if the channel selector is
in the "2" position.

The sigh function is provided by a sigh
timer which is controlled by mixer switch SW' and
control knobs 29' and 30'. When the switch SW' is on
and the control switch 13' is set on channel 1, the
setting of knob 29' provides a first predetermined
period of time to elapse during which the system
operates on channel 1. At the end of the first
predetermined period of time, the sigh timer causes
the machine to change to channel 2 for a second
predetermined period of time as set by control knob
30'. After the second predetermined period of time
has elapsed, the machine reverts to operation on
channel 1 for the first predetermined period of time.
The system continues cycling between the channels 1
and 2 as long as the switch SW' is in the on position.
An LED indicator 31' indicates when the switch SW' is
in the on position.

An airway pressure gauge 32' is provided to
monitor breathing circuit pressure. The fuse 34
protects the entire machine. The sensor output jack
33' permits connection of an oscilloscope or other

measuring device for determining the volume displacement and/or piston or diaphragm position of a linear motor.

Referring to Figure 4 of the drawings which schematically shows the circuitry of the ventilator 10' there is shown a signal generator 11' having a frequency range of about 45-3000 breaths per minute. The frequency on channels 1 and 2 is about 0.5-50 Hz. The percent inspiration for channels 1 and 2 is about 25%-75%. The percent power range for channels 1 and 2 is about 3%-99%.

The signal produced by the signal generator 11' shown in Figure 4 is a constant voltage, variable frequency, variable period square wave. This signal passes to an amplifier 18' connected to the signal generator. As discussed above, the power gain for channels one and two is adjusted by control knobs 20' and 21', respectively. The signal generated by the amplifier 18' is directed to a polar converter 22' which is connected to the amplifier. The polar converter 22' serves a dual function of polarizing the square wave and providing the connection between the power supply and the linear motor or oscillator 23'. The linear motor 23' includes a diaphragm 24' which converts mechanical motion to pressure waves in the gas.

Oxygen or compressed gas is added to the system through line 26' which is connected to line 25'. The line 28' allows pressure on both sides of the diaphragm to equalize to the mean airway pressure

in respirator line 25'. Orifices 28'' and 28'''
restrict flow to the pressure chamber of the oscillator
and pressure gauge 32' respectively. It is understood
that the line 25' is connected through suitable
medical apparatus to an endotracheal tube or the like
to provide breathing function.

The circuits in the system of Figure 4 can
be realized by use of diagrams similar to those of
Figures 11 and 12, as would be apparent to one of
ordinary skill in the art.

The high frequency ventilator 10' shown in
Figure 3 includes a stainless steel cabinet C having a
ventilating screen S attached to the side thereof.
The high frequency ventilator 10' operates substantially
the same as the ventilator 10 shown in Figure 1 so
corresponding reference numerals are used for
corresponding components with the addition of a prime
('). Something added to the ventilator as shown in
Figures 3 and 4 compared to the ventilator shown in
Figure 1 is the position sensor 35', which is explained
later, and the volume and excessive power circuit 36',
also explained later.

Referring to Figure 13, which is a schematic
representation of an embodiment of the circuit which
connects a patient to the invention, the outlets of
the machine as shown as 25' on Figure 3 is connected
to point 496. Air, oxygen, anesthesia gas, medicine
gas or a combination of gases is introduced into the
circuit at point 481. Throttling valve 482 determines

the amount of gas introduced. The gas enters
humidifier 483 which can be a cascade type of conven-
tional design that bubbles the gas through heated
water which heats it and raises its relative humidity
to 100%. The gas then enters the connecting tube 484.
If the flow is too great for the pre-selected maximum
system pressure, relief valve 485 will open thereby
venting the excess flow. The gas is available at
adapter 486 and may enter a mouthpiece or endotracheal
tube 487 as shown. Endotracheal tube 487 has an
inflatable cuff 488 which is inflated by syringe 489
to seal the tube 487 in the airway for communication
with the lungs of the patient 495. Gas is allowed to
exit the system by first passing through filter 490.
Since the flow through the system is very little, it
would be possible for a bit of mucous or other secre-
tion to obstruct the small passages in throttling
valve 493. Therefore, filter 490 provides a large
area for any such secretions to collect rendering a
hazard from them unlikely. The filter 490 may be a
small mesh brass cloth filter. The gas then passes
through check valves 491 and 492 which prevent air
entrainment during the reverse pulse of the machine.
The system pressure is controlled by throttling valve
493 which opens to the atmosphere.

Referring to Figure 7 of the drawings there
is shown another embodiment of the invention. This
embodiment of the invention in addition to including
the high frequency ventilator of the invention also
includes a volume ventilator. The ventilator includes

a cabinet or housing 200 which may be made of stainless
steel or other suitable material. The instrumentation
on the housing is explained as follows.

An hour meter 201 is provided to record the
total operating time. A master alarm light 202 is
provided to flash for all alarms and a tone is
generated by horn 202'. Alarm lights 203, 204, 205
and 206 flash for malfunction of power supplies. Alarm
light 207 flashes when oxygen pressure is failing.
Alarm light 208 flashes when the air line pressure is
failing. Toggle switch 209 allows selection between
the high frequency ventilator, the volume ventilator
or a combination of the ventilators. Indicator light
210 indicates when the high frequency ventilator is in
operation, indicator light 211 indicates when the
volume ventilator is in operation and indicator light
212 indicates when both the high frequency and volume
ventilators are in operation.

Thorpe tube flow meter 213 indicates the
flow rate adjustment for the high frequency gas
entrainment. Airway pressure gauge 214 is used to
monitor the breathing circuit pressure. The master
power switch 215 turns the machine on and off. LED
indicator light 215a indicates when the machine is on.
An alarm light 215b and horn may be provided to alert
an operator when the switch 215 is turned on and the
power source is not connected.

Toggle switch 218 activates the automatic
channel selecting circuit. LED indicator light 218'
indicates when the channel selector is on. Control
knob 216 controls the operation time of channel 1.

It provides for the operation of channel 1 up to about
1 hour. A channel 2 duration knob 217 is also provided
to control the operation time of channel 2 up to about
6 minutes.

Control 219 increases the channel 1 frequency
when rotated in the clockwise direction. Control 220
similarly increases the channel 2 frequency when
rotated in the clockwise direction. Indicator lights
221 and 222 indicate operation of channel 1. Indicator
lights 223 and 224 indicate operation of channel 2.
Digital meter 225 indicates the frequency in cycles
per second of the channel whcih is operating.

Control knob 226 when rotated in a clockwise
direction increases the channel 1 percent of inspira-
tion. Similarly control knob 227 when rotated in the
clockwise direction increases the channel 2 percent
inspiration. Digital meter 228 indicates the percent
inspiration for the channel which is operating.
Indicator lights 229 and 230 indicate the operation of
channels 1 and 2 respectivley.

Control knob 231 increases the channel 1
drive power when rotated in the clockwise direction.
Similarly control knob 232 increases the channel 2
drive power when rotated in the clockwise direction.
The percent power is shown on the digital meter 233.
Indicator lights 234 and 235 indicate the operation of
the first and second channels respectively. Indicator
light 236 indicates when the piston is at either
extreme of its travel.

Toggle switch 237 switches on a low humidity alarm. Alarm light 238 indicates when the low humidity alarm is tripped. Control knob 239 blends oxygen and air to give a variable percent oxygen. Toggle switch 240 arms the sigh function. Indicator light 241 indicates when the sigh function is in progress. Switch 242, when depressed, provides a manual sigh.

Control knob 243 increases the sigh volume when rotated clockwise. Indicator lights 244, 246 and 248 light when the switch 240 is on. Control knob 245 selects the number of sigh breaths for each sigh cycle. Control knob 247 selects the number of sigh cycles per hour. When switch 240 is on the time set by control 247 begins to run. After the set time period expires, control of the entire machine is assumed by the settings on controls 243 and 245. The machine then gives the patient the number of breaths designated by control 245 of the volume designated by control 243 after the completion of which control of the machine is returned to the appropriate mode set by switch 209. The time set by control 247 then begins to run again to repeat the cycle. The manual sigh switch 242 overrides the time delay set by control 247 to cause the sigh function to commence when depressed. When the switch 242 is depressed, and after the sigh cycle is completed, the time delay begins again at zero.

The mean airway pressure digital meter 249 shows the airway pressure in centimeters of water. Control knob 250 sets the low pressure alarm limit

which causes alarm light 251 to flash when the low pressure limit has been reached. Control knob 252 sets the high pressure alarm limit and alarm light 253 flashes when the high pressure limit is reached. Control knob 254 sets the airway temperature alarm level and alarm light 255 flashes when the preset temperature range is exceeded. Control knob 256 increases the airway temperature when rotated in the clockwise direction. Digital meter 257 indicates the airway temperature in degrees centigrade.

Control knob 258 sets the body temperature alarm level. Alarm light 259 flashes when the body temperature exceeds the present range. Control knob 260 calibrates the body temperature readout. Indicator light 261 is on when the body temperature monitor is on. Digital meter 262 indicates the body temperature in degrees centigrade.

The hour meter 201 provides continuous monitoring of the instrument operating time. It may be used for recording patient time and for recommended service. The master alarm light 202 illuminates when any alarm function is tripped. This may be a bright red light which flashes in conjunction with an intermittent tone generated by a horn 202 to gain the attention of the attendant in charge. Once the operator has returned to the ventilator he will find that an additional alarm light will be illuminated at the precise location of the function causing the alarm. The following alarms are also installed to insure maximum patient safety. The power supply alarms 203, 204, 205 and 206 when illuminated indicate

that a power source for the machine electronics has
failed and another machine should be brought in
immediately. The oxygen and air low line pressure
lights 207 and 208, respectively, are provided to
alarm the machine operator that the hospital oxygen or
air gas supply has dropped below about 35 PSI. The
ventilator will function normally until the pressure
is below 25 PSI. Therefore, this gives adequate
warning for patient safety. For the humidity alarm,
the humidity alarm LED 238 flashes when the relative
humidity in the patient's inspired gas drops below
safe limits. This notifies the therapist to check the
system humidifier and reservoir for proper operation
and water supply. For the airway pressure alarm,
changes in airway pressure generally occur when either
the ventilator or patient has undergone a change that
will require immediate attention. Changes in airway
pressure that are either high or low could be life
threatening so adjustable alarms 250 and 252 have been
provided for low and high pressure respectively. The
airway temperature alarm provides notice when the
inspired gas temperature has gone out of range.
Increasing cooling or heating will cause a change in
the body's temperature so that monitoring is necessary.
The body temperature alarm is provided since airway
temperature may cause changes in body temperature.
The expired volume alarm 270 is provided to tell the
operator if the patient expiration decreases or
ceases. When this alarm is activated, there is

usually an accidental disconnection of the patient
from the ventilator and immediate action is required.
Because of the urgency, extra light and sound are
generated.

When master power switch 215 is on, a green
LED 215a above the master switch 215 glows. However,
in the event of an AC power failure, the red LED light
215b below the siwtch 215 will flash accompanied by an
intermittent tone from horn 202'.

The mode control switch 209 changes the
ventilator from standard breathing to high frequency
breathing. Standard breathing rates may also be
combined with high frequency rates by moving the mode
selector to the combined position. When this is done,
the patient may receive the benefit of both ventilators
simultaneously.

The high frequency gas flow is controlled by
a Thorpe tube flow meter 213. The gas flow rate is
adjustable from zero to 15 liters per minute (LPM).
Increasing flow provides more fresh air for the
patient to breathe. Adequate flow is required or the
patient will begin to re-breathe his expired air. A
blood gas analysis should be used to determine the
patient's oxygen and carbon dioxide level for proper
adjustment.

The airway pressure gauge 214 is used to
monitor the patient's airway pressure during each
cycle of the ventilator. This is a reliable mechanical
gauge which may also be used to cross-check the mean
airway pressure digital meter 249.

The frequency digital meter 225 provides a
precise measurement of the number of cycles per
second. The rate may be changed with control knobs
219 and 220 for chanels 1 and 2, respectively. The
selector switch SW controls which channel is used.
When the high frequency ventilator is operating the
LED 221 or 223 lights above the control in use.
Increasing frequency generally reduces tidal volume
and increases the carbon dioxide level in the blood.

The percent inspiration digital meter 228
provides readout and adjustment for setting the high
frequency inspiration versus expiration time. When
the machine pushes air forward, it is called
inspiration, and when it pulls backward, it is called
expiration. Therefore, the amount of time the
ventilator works in either direction can be adjusted.
LED lights 229 and 230 indicate which control for each
of the channels is in use. Varying the ratio of
inspiration to expiration causes changes in airway
pressure. Also medicine and secretions such as mucous
may be transported either into or out of the lungs at
certain ratios. This may be used to enhance secretion
clearance from the lungs.

The percent power digital meter 233 and the
controls 231 and 232 provide readout and adjustment
for the amount of drive power applied to the oscillator.
The excessive power indicator LED 236 flashes when the
piston is at either extreme of its travel. LED lights
234 and 235 designate the control in use. Increase in
the operating power reduces the patient's carbon
dioxide level in the blood and has little effect on

the oxygen level. Therefore, carbon dioxide levels can be changed without changing the oxygen level. The percent oxygen control 239 is used to adjust the percentage of oxygen desired in order to maintain proper oxygenation of the patient. When this control is used oxygen flow leaving the ventilator can be changed to any desired concentration between 21% and 100% oxygen. If the patient's oxygen level is too low an increase with this control will raise his oxygen level.

The sigh module consists of switches 240 and 242, an "in progress" LED light 241 and LED indicator lights 244, 246 and 248 and their controls 243, 245 and 247. The first switch 240 is used to turn on the sigh module. The red push button switch 242, will give a manual sigh when depressed. The volume control 243 is used to adjust the sizes of the breaths from zero to 3 liters. The breaths control knob 245 allows the operator to set the number of breaths from 1 through 4 breaths per sigh cycle. The delay control knob 247 is used to adjust the amount of time that will pass before the next sigh cycle will begin. Time is adjustable from zero minutes to about 1 hour.

The sigh cycle helps prevent lung collapse. When a patient is ventilated automatically, with a constant volume, his alveoli need to be expanded occasionally. The sigh accomplishes this.

The digital meter 249 provides a pressure reading for the patient's average airway pressure. Because patients can be ventilated at lower pressures using high frequency, an accurate indicator for mean airway pressure is necessary. The operator can use this meter to maintain pressure within safe limits.

The digital meter 257 gives a direct
temperature reading in centigrade degrees of the gas
going to the patient. Keeping the inspired air at
body temperature is required to prevent hypothermia.

The body temperature digital meter 262
displays the patient's body temperature by using a
probe 276 placed on the patient's body. The patient's
temperature is measured with an ordinary thermometer
and that temperature is set on the digital meter with
the calibrate control 260. Body temperature can be
affected with high frequency ventilation. Therefore,
body temperature monitoring is desirable.

The volume control knob 263 found in the
volume ventilator section is used to adjust the
patient's breath volume from zero to 3 liters per
breath. As the breath volume is increased, the
patient's oxygen level increases and his carbon dioxide
decreases. The continuous mandatory ventilation/
intermittent mandatory ventilation (CMV/IMV) control
264 regulates the breaths per minute allowing the
operator to select any breath rate between 2 and 60
breaths per minute. Increasing the rate control will
increase the patient's ventilation. This causes the
patient's oxygen level to rise and his carbon dioxide
level to decrease. The flow control knob 265 varies
the speed that air flows from the ventilator to the
patient during inspiration. This speed is adjustable
from zero to 150 liters per minute. Increasing the
speed causes inspiration to take less time. This
control is normally adjusted to give the patient a
comfortable inspiration rate.

The sensitivity control knob 266 adjusts the volume ventilator so that it can operate manually when the patient's efforts to breathe are good enough not to need automatic ventilation. Increasing sensitivity makes it easier for the patient to breathe on his own. The positive and expiratory pressure/continuous positive airway pressure (PEEP/CPAP) are adjustable from 1 to 50 centimeters of water. This is residual pressure in the lungs at the end of expiration by the patient. It is required when a patient is in danger of a lung collapse or is recovering from one. Use of PEEP or CPAP means that the air pressure inside the patient's lungs is always kept above zero, thereby holding them open. The nebulizer control 268 varies the medicine aerosolization rate to the patient. The more it is increased the faster the patient receives his medicine. The intermittent mandatory ventilation delay (IMV delay) is controlled by knob 269. When the patient begins to breathe on his own, it is a good policy to have an automatic takeover in case of relapse; it is also wise to give him a synchronized breath (with his own) at a given interval. The control knob 269 allows the machine to search for up to 10 seconds for a patient inspiration before it cycles on its own.

The volume ventilator section is as follows. Control knob 263 increases the tidal volume. Control knob 264 increases the CMV/IMV breaths per minute. Control knob 265 increases the inspirator flow rate and decreases the inspiratory time when rotated counterclockwise. Control knob 266 increases the

sensitivity of the volume ventilator to the inspiratory
effort when rotated in the clockwise direction.
Control knob 267 increases the PEEP/CPAP pressure when
rotated in the counterclockwise direction. Control
knob 268 increases the medicine nebulizer flow when
rotated in the counterclockwise direction. Control
knob 269 increases the IMV search time for patient
inspiratoin when rotated in the clockwise direction.
Alarm light 270 lights to alarm for loss of patient
expiration.

The common section of the high frequency and
volume ventilators is composed of accessory components
that are used during either high frequency or volume
ventilation. These inlcude the following:

1. Humidity Alarm
2. Low Airway Pressure Alarm
3. High Airway Pressure Alarm
4. Airway Temperature Alarm
5. Body Temperature Alarm
6. Air and Oxygen Blender
7. Manual and Automatic Sigh
8. Digital Displayed Mean Airway Pressure
9. Digital Displayed Airway Temperature
10. Airway Temperature Control
11. Digital Displayed Body Temperature
12. Body Temperature Calibrate

The humidity alarm utilizes an electronic
sensor to analyze the water vapor content of the
inspired air passing from the main stream humidifier
to the patient. The humidity alarm chamber contained

in the high frequency ventilator is updated on a
continuous basis during high frequency ventilation and
breath by breath during volume ventilation. The alarm
is scaled to activate when relative humidity drops
below about 80%. The alarm may be turned on and off
with the humidity alarm toggle switch 237.

The low airway pressure alarm is used to
monitor minimum airway pressure during high frequency
and volume ventilation. The alarm is adjustable from
about zero through 50 centimeters of water. When the
alarm is tripped, a warning sound and a warning light
251 are activated to draw attention to the control.

The high airway pressure alarm is used to
monitor maximum airway pressure during high frequency
and volume ventilation. The alarm is adjustable from
about 20 through 70 centimeters of water. When the
alarm is tripped, a warning sound and a warning light
253 are activated to draw attention to the control.

The airway temperature alarm is used to
monitor airway temperature during high frequency and
volume ventilation. The alarm is adjustable from about
34° Centigrade to 40° Centigrade. When the alarm is
triggered, a warning sound and a warning light 255 are
activated to draw attention to the control.

The body temperature monitor is used to
monitor body temperature during high frequency and
volume ventilation. The alarm is adjustable from 34°
Centigrade through about 40° Centigrade. When the
alarm is triggered, a warning sound and a warning
light 259 are activated to draw attention to the
control.

The air and oxygen blender 239 is a dual
mixture control capable of delivering 200 LPB flow
rates and concentrations form 21% to 100% oxygen. The
system incorporates dual alarms for air and oxygen low
line pressure which when activated emit a warning
sound and warning lights 207 or 208 to notify the
operator of the problem.

The manual and automatic sigh module
controls patients sighing. There are variable
controls for tidal volume, number of breaths per sigh
and sigh delay interval. The tidal volume control 243
is adjuatable from zero cc's to 3,000 cc's. The
breaths control knob 245 is adjustable from 1 to 4
breaths per sigh. The delay control knob 247 is
adjustable between zero minutes and 1 hour. When the
sigh toggle switch 240 has been turned on, the lights
244, 246 and 248 will be illuminated to indicate that
the sigh module has been activated. To test the sigh
or to manually sigh the patient, you need merely press
the manual red push button 242 to interrupt the set
high frequency or volume ventilation and begin to
cycle. Once the sigh program has been completed, the
high frequency or volume ventilator will return to
normal operation and the light 241 will go out. The
digital display 249 for the mean airway pressure is
used for reading airway pressure changes during high
frequency or volume ventilation. The internal
transducer also combines with the low and high airway
pressure alarms to monitor the maximum and minimum
airway pressures.

The digital display 257 for airway temperature is used to monitor end airway temperature. The airway temperature sensor 310 is placed near the patient's mouthpiece so that an accurate temperature is monitored.

The airway temperature control 256 located below the digital display 257 is used to adjust the humidifier temperature to raise or lower the airway temperature. The digital display 262 for body temperature displays the patient's body temperature. A body temperature sensor 276 is placed somewhere on the body and the patient's temperature is taken manually. The body temperature calibration control 260 is used to set in the patient's body temperature after which the digital display will track the changes in body temperature. During high frequency and volume ventilation care must be taken to prevent hypothermia.

The volume ventilator is a pneumatically powered and electronically governed volume ventilator. It is capable of delivering smooth inspiratory power at flow rates up to 200 LPM and prssures up to 120 centimeters of water.

The volume ventilator has an electronic or pneumatic controls for the following functions:

1. Tidal "Volume"
2. "CMV/IMV" Rate
3. Inspiratory "Flow"
4. Patient "Sensitivity"
5. "PEEP" (Positive End Expiratory Pressure)
6. "Nebulizer" flow rate
7. "IMV Delay"

The ventilator also incorporates an expired volume alarm 270. The volume control 263 governs the size of the tidal volumes which are delivered by the ventilator. The sizes of these breaths can range from zero cc's to 3,000 cc's. The CMV/IMV breaths per minute control 264 is used to regulate the number of breaths per minute being delivered to the patient. The control is used for either continuous mandatory or intermittent mandatory ventilation.

The inspiration flow control knob 265 regulates the speed at which air travels from the ventilator to the patient. The maximum inspiration flow rate is approximately 200 LPM.

The patient sensitivity control knob 266 is used to regulate the necessary effort required by the patient to activate the ventilator. This effort may be overriden or adjusted as sensitive as .5 centimeters of water.

The PEEP valve which is controlled by control knob 267 is used to control end expiratory pressure during volume ventilation and for adjusting mean airway pressure during high frequency ventilation. The nebulizer flow rate control knob 268 regulates flow to the medicine nebulizer. Increase in the flow will generate an increase in medicine to the patient. The IMV delay control 269 is used to help synchronize the IMV breath with the patient's actual breathing. The IMV delay can be set to search for up to 10 seconds before inflating the patient's lungs. IMV delay is intended to reduce the risk of inflating the patient during a normal expiration.

The expired volume alarm light 270 and
interconnected expired volume alarm horn are used to
detect the loss of exhalation from the patient. When
the expired volume alarm is triggered the master alarm
light 202 and the expired volume light 270 are illumi-
nated. Also the master alarm horn 202' and the
expired volume alarm horn are activated. The master
alarm light 202 and horn 202' and the expired volume
alarm light 270 and horn will operate intermittently
and out of phase to increase maximum notice.

The high frequency ventilation may be
coupled with aerosol therapy for benefits in two
areas. The first area is in particle distribtion.
Aerosol particles introduced into the lungs tend to be
deposited rather than exhaled when coupled with high
frequency ventilation. Certain percent inspirations
will cause aerosol droplets forming in the
endotracheal tube to move down the tube and into the
lungs. The second area is in mucocilliary clearance.
At certain percent inspirations the ventilator will
cause liquid outflow from the lungs. Mucous can be
removed from a lung into the ET tube and subsequently
out of the patient.

The high frequency oscillator piston position
is sensed by the piston sensor 228. The signal from
the position sensor is fed into one channel of an
oscilloscope 271 shown in Figures 7 and 8. The
acoustic probe 272 picks up the vibration in the
patient's chest and the analog signal conditioner 273
feeds the other channel of the oscilloscope. The
controls of the oscillator are then varied until both

signals are in phase with one another. This allows
rapid establishment of optimum oscillator parameters
to overcome asympathetic harmonic vibrations in the
airways which inhibit ventilation. This method may be
used as an internal component of a high frequency
ventilator or as an external system. Control knob 274
is provided to turn the oscilloscope 271 on and off.
The display mode volume wave form is determined by
control knob 275.

The patient's body temperature is monitored
as shown in Figure 9. A temperature sensor 276 is
provided for connecting with the patient. The
calibrate control knob 260 adjusts the monitor to the
temperature measured conventionally. The control knob
258 turns the monitor on and sets the alarm. The
monitor tracks the body temperature. If the
temperature varies plus or minus one degree Centigrade,
the alarm circuit 277 triggers the ventilator master
alarm 202 to alert the operator. The sensor 276 is
the only external component. The advantages of the
temperature meter and display are that they provide
real time constant temperature dipslay, it is
integrated with the ventilator, the alarm may be used
for rise or fall of temperature, it monitors the
ventilator as well as the patient and the non-
intrusive sensor 276 may be taped to the body of the
patient.

Pneumatic circuitry of the ventilator is
schematically shown in Figure 10. The device includes
a low pressure alarm 278 connected to the air inlet
line 279. Regulators 280 and 281 are provided to

control the incoming air. A low pressure alarm means
282 is connected to the oxygen inlet line 283.
Regulators 284 and 285 are connected to the oxygen
line. The air and oxygen lines are in turn connected
to an oxygen blender 286 controlled by knob 239. The
oxygen blender is connected to solenoid valve flow
meter 287 and the solenoid valve 288 which goes to the
ventilator. The oxygen blender 286 is also connected
to solenoid valve 289. Solenoid valve 289 controls
the posititve end expiratory pressure (PEEP). A flow
meter 213 receives flow from the solenoid valve 287.
A needle valve nebulizer 291 controlled by knob 268 is
provided to receive flow from the solenoid valve 289.
A medicine nebulizer 292 is provided for nebulizing
medicine. Solenoid valve 288 is connected to line 293
which goes to a needle valve 294 for regulating the
flow rate. The needle valve 294 is in turn connected
to pneumotach 295. The pneumotach 295 is connected to
a volume transducer 295a which gives an electronic
signal to close the solenoid valve 288. The pneumotach
295 is also connected to the airway line 296. The
line 293 is connected to exhalation solenoid valve 297
which exhausts to the atmosphere. The solenoid valve
289 is connected through line 298 to orifices 299 and
300. The orifice 299 goes to a needle valve 301
controlled by knob 267 which goes to the orifice 302
which exhausts to the atmosphere. The orifice 300
goes to the solenoid valve 290 for the oscillator 23'.
A pressure relief valve 303 is provided to exhaust to
the atmosphere. The three-way solenoid valve 290 is

connected to the mean airway transducer 304 which
gives an electronic signal for the mean airway
pressure. A needle valve 305 controlled by knob 266
is provided for the inspiration sensitivity. Pressure
switch 306 is also provided for the inspiration
sensitivity. The high frequency oscillator 23' is
connected to pressure gauge 214. Pressure release
valve 308 is also provided to relieve excess pressure.
A conventional humidifier 309 is provided in the
airway line. The airway temperatures sensor 310
detects the temperature in the airway. An exhalation
valve 311 is provided and is closed by pressure. The
exhalation valve 311 is connected to the expiration
alarm 312 which is vented to the atmosphere. The
airway line 296 is connected to an endotracheal tube
313 which goes down the throat of the patient and into
the airway into the bronchial tubes.

When the mode switch is in the high frequency
position, the solenoid valve 287 is open (only time it
is open). When the mode switch is in the combination
position, solenoid valve 287 closes, solenoid valve
288 opens, and solenoid valve 289 opens.

When the mode switch is on the volume only
position, solenoid valves 288 and 289 are open. Lines
314 and 315 are connected by the three-way solenoid
valve 290.

The high frequency ventilator of the
invention has been designed to operate in a variety of
configurations which will enhance ventilation and
oxygenation above the levels of current technology.

The ventilator has been designed to cover a wide degree of variables yet operate with simple, predictable and minimal controls. The ventilator is also constructed to withstand the abuse that it will receive while in hospital use.

EXPERIMENTAL TEST RESULTS

The high frequency ventilator of the present invention has been tested at major medical facilities and shown effective in four major applications. They are:

1) Mucociliary transport and secretion and medicine transport. The machine has been shown to effectively cause substances to be moved out of or into the lungs depending upon the therapist's desires.

2) Acute respiratory failure. The machine has been shown to be a safe and effective ventilatory means for maintaining life after severe lung injuries.

3) Hyaline Membrane Disease. The machine has been shown to provide a safe and effective means for respiration of infants with HMD.

4) Anesthesia Delivery. The machine has been shown to be a safe and economical means for delivery of anesthesia and enhancing the recovery process during surgical procedures and other procedures requiring general anesthesia.

During eleven experiments, mongrel dogs
weighing 20 to 40 Kg were chronically instrumented
with endocordial crystals implanted in the left and
right ventricles of the heart to evaluate the shape
changes of the ventricles during high frequency
ventilation. The dogs were acutely anesthetized and
paralyzed and placed on high frequency ventilation at
20 Hz to 30 Hz, 50% inspiration and power as required
for proper CO_2 elimination with 5 liters per minute
airflow and FIO_2 (fraction of inspired O_2) + 1.0.
Mean airway pressures were varied from 4 to 40 cm H_2O
and heart dimensions were recorded. The machine
provided ventilation during these experiments.

The machine was used during various surgical
and anesthesia procedures on 14 dogs and 4 cats at
frequencies ranging from 5 to 50 Hz and at various %
inspirations. The procedures and results are as
follows:

1) Gut resection, 60 lb doberman dog.
Intestinal blockage diagnosed 3 weeks
prior to procedure and deemed to be a
very high surgical and anesthesia risk.
The machine was combined with an Ohio
anesthesia machine to deliver Metafane
gas. The patient was ventilated for 1
hour 40 minutes at 30 Hz and recovered
uneventfully.

2) Dental prophylaxis, 5 lb, 10 year old
Dachshund male dog. The patient was
entubated and paralyzed with succinyl-
choline at 20 Hz during the procedure
and recovered normally.

3) Dental prophylaxis, 15 lb, 14 year old
Schnauzer male dog. Same as 2 above
except ventilation period was 1 hour and
5 minutes.

4) Panhysterectomy, feline, 5 lbs. The
machine was used to deliver Metafane gas
from an Ohio anesthesia machine. The
patient was ventilated at 30 Hz for 30
minutes and has an uneventful recovery
with same day discharge.

5) Umbilical hernia repair, 1 lb English
Sheep Dog, 2 weeks old. Delivered
Metafane gas from an Ohio anesthesia
machine. The patient was ventilated at
15 Hz for 5 minutes, 50 Hz for 15 minutes
and 15 Hz for 5 minutes and had an
uneventful recovery.

6) Same as 5) above.

7) Dental prophylaxis and granulomatous
keratatis, 40 lb Toy Poodle, 11 years old.
Delivered Metafane gas for ventilation
and anesthesia during procedures.
Patient was ventilated at 30 Hz for 15
minutes with an uneventful recovery.

8) Panhysterectomy, 20 lb mongrel dog.
Ventilation and anesthesia using
Metafane gas during procedure. Patient
was ventilated at 30 Hz for 15 minutes,
20 Hz for 10 minutes and had an unevent-
ful recovery.

9) Panhysterectomy, 35 lb mongrel dog.
The machine was used to deliver Metafane
gas for anesthesia and to provide
ventilation during the procedure. The
patient was ventilated at 30Hz for 20
minutes and 5 Hz for 2 minutes and had
an uneventful recovery.

10) Lipoma, 10 lb Poodle, 13 years old male.
Metafane used for anesthesia. The
patient was ventilated at 20 Hz for 20
minutes and at 5 Hz for 5 minutes.
Recovery was uneventful.

11) Panhysterectomy, 35 lb dog. The machine
was used to deliver Metafane gas for
anesthesia and to provide ventilation
during the procedure. The patient was
ventilated at 5 Hz for 5 minutes, 20 Hz
for 5 minutes, 30 Hz for 10 minutes and
5 Hz for 2 minutes. The recovery was
uneventful.

12) Panhysterectomy, 6 lb feline. The
machine was used to deliver Metafane gas
for anesthesia and to provide ventilation
during the procedure. The patient was
ventilated at 30 Hz for 10 minutes, 20
Hz for 10 minutes and 5 Hz for 5 minutes.
The recovery was uneventful.

13) Panhysterectomy, 5 lb feline. Similar
to 12) above except that ventilation was
at 30 Hz for 20 minutes with an
uneventful recovery.

14) Multiple mammary carcinoma excisions and
panhysterectomy, 65 lb Afghan Hound.
The machine was used to deliver Metafane
gas for anesthesia and to provide
ventilation during the procedures. The
patient was ventilated at 20 Hz for 20
minutes, 5 Hz for 5 minutes, 20 Hz for
15 minutes and 5 Hz for 3 minutes. The
recovery was uneventful.

15) Panhysterectomy, 3 lb feline. Similar
to 12) above except that ventilation was
at 20 Hz for 20 minutes with an uneventful
recovery.

16) Lipoma and holodendron cauterization,
10 lb miniature Schnauzer. The machine
was used to deliver Metafane gas for
anesthesia and to provide ventilation
during the procedures. The patient was
ventilated at 20 Hz for 15 minutes and
5 Hz for 10 minutes. Recovery was
normal.

17) Multiple mammary adenocarcinoma
excisions, 2 lb Yorkshire Terrier. The
machine was used to deliver Metafane gas

and to provide ventilation. The patient
was ventilated at 20 Hz for 15 minutes
and 5 Hz for 5 minutes. Recovery was
normal.

18) Panhysterectomy, 3 lb Poodle. The
machine was used to deliver Metafane gas
for anesthesia and to provide ventilation
at 20 Hz for 15 minutes and at 5 Hz for
5 minutes. Recovery was normal.

Another series of experiments were performed
to determine if oleic acid injury dogs could be
ventilated by high frequency oscillation.

Fifteen dogs of about 9 Kg weight were
anesthetized and treated with oleic acid. After 1
hour of unassisted breathing, they were ventilated by
the machine for 4 hours. After each experiment was
concluded, additional frequencies, % inspirations and
power settings were used to establish ventilatory
parameters.

Typical blood gases for the first four
animals were as follows:

1 HOUR AFTER OLEIC ACID

Hz	%I (inspirated)	%P (power)	FIO_2 (fraction of inspired O_2)	pH (of blood)	$PaCO_2$ (arterial pressure of CO_2 in cm H_2O)	PaO_2 (arterial pressure of O_2 in cm H_2O)
NORMAL BREATHING			.65	7.32	43	57
NORMAL BREATHING			.48	7.30	38	73
NORMAL BREATHING			.86	7.29	46	63
NORMAL BREATHING			.81	7.14	51	91

1 HOUR ON HFV (HIGH FREQUENCY VENTILATION)

Hz	%I	%P	FIO_2	pH	$PaCO_2$	PaO_2
10	33	75	.37	7.30	41	124
10	33	75	.32	7.34	39	135
10	33	75	.36	7.29	42	117
10	33	75	.34	7.28	34	100

2 HOURS ON HFV

DOG	Hz	%I	%P	FIO_2	pH	$PaCO_2$	Pa(
1	10	33	65	.37	7.35	36	11:
2	10	33	75	.32	7.28	41	13(
3	10	33	55	.35	7.30	37	13(
4	10	33	45	.35	7.28	33	13S

3 HOURS ON HFV

DOG	Hz	%I	%P	FIO_2	pH	$PaCO_2$	PaC
1	10	33	65	.38	7.36	29	100
2	10	33	65	.32	7.34	41	89
3	10	33	65	.37	7.30	35	126
4	10	33	65	.34	7.16	37	127

4 HOURS ON HFV

DOG	Hz	%I	%P	$FIO2$	pH	$PaCO_2$	PaC
1	10	33	65	.38	7.29	34	161
2	10	33	65	.26	7.31	42	101

10	33	65	.36	7.32	36		95
10	33	65	.34	7.24	45		80

5th HOUR EXPERIMENTS

G	Hz	%I	%P	FIO$_2$	pH	PaCO$_2$	PaO$_2$
	5	33	80	1.0	7.55	18	450+
	10	33	80	1.0	7.50	22	450+
	15	33	80	1.0	7.50	25	450+
	20	33	80	1.0	7.45	35	450+
	25	33	80	1.0	7.35	45	450+
	30	33	80	1.0	7.25	50	450+
	35	33	80	1.0	7.15	55	450+
	40	33	80	1.0	7.05	65	450+
	45	33	80	1.0	7.00	75	450+
	50	33	80	1.0	6.95	90	450+

5	50	80	1.0	7.55	18	450+
10	50	80	1.0	7.50	22	450+
15	50	80	1.0	7.49	24	450+
20	50	80	1.0	7.47	32	450+
25	50	80	1.0	7.40	35	450+
30	50	80	1.0	7.35	45	450+
35	50	80	1.0	7.25	55	450+
40	50	80	1.0	7.15	60	450+
45	50	80	1.0	7.10	70	450+
50	50	80	1.0	7.00	80	450+
5	75	80	1.0	7.45	35	450+
10	75	80	1.0	7.40	40	450+
15	75	80	1.0	7.35	45	450+
20	75	80	1.0	7.30	50	450+
25	75	80	1.0	7.25	55	450+
30	75	80	1.0	7.20	60	450+

35	75	80	1.0	7.10	65	450+
40	75	80	1.0	7.00	75	450+
45	75	80	1.0	6.95	85	450+
50	75	80	1.0	6.90	100	450+

Another experimental series was conducted on 3 dogs to determine if blood gas values are maintained during a full range of frequency, % I and power settings. Methods and results summaries are as follows:

1) The dog was anesthetized with surital. The animal was placed on the ventilator for two hours and received 40% humidified oxygen, blood pressure, esophageal pressure, ECG, end tidal O_2 and CO_2 were continuously monitored. Ventilator settings were 5 and 15 Hz, Full Power and I:E ratios of 55:50, 70:30 and 30:70.

Results:

a) The dog was well ventilated.
b) Blood gas analysis was done for each setting.
c) In all cases PO_2 remained high and PCO_2 was low.

2) The dog was anesthetized with surital and placed on the ventilator for two hours. The animal received 40% humidified oxygen. Blood pressure esophageal pressure and end tidal 02 and CO_2 were monitored.

A full range of frequency settings and I:E ratios were used at full power.

Results:

a) The dog was well ventilated throughout the experiment.
b) The capabilities of the ventilator were demonstrated.

3) A dog was anesthetized with surital and paralyzed with curare. The animal was placed on the ventilator for two hours. Blood pressure, esophageal pressure, ECG and rectal temperature were monitored. The animal was on a high impedance bias flow circuit and received 100% humidified oxygen.

Results:

a) The dog was well ventilated throughout the course of the experiment.

b) The animal was ventilated at 5 Hz, Full power and I:E ratio of 50:50.

Another experimental series was conducted on 6 dogs to study the effect of different % Inspiration settings on tracheal transport rates methods and results summaries are as follows:

1) A dog was anesthetized with surital and paralyzed with curare. The animal was placed on the ventilator for three hours and received 100% humidified oxygen. Blood pressure, esophageal pressure, ECG, rectal temperature and end tidal CO_2 were continuously monitored. Several times during the study a droplet of radioactive iron oxide was instilled in the trachea and its movement was monitored with a tracheal probe and recorded.

Results:

a) The dog was well ventilated throughout the course of the experiment.

b) The animal was ventilated at 5 Hz, full power and I:E ratios of 50:50, 70:30 and 30:70.

c) In all cases mucus moved up the trachea.

2) A dog was anesthetized with surital and paralyzed with curare. The animal was - placed on the ventilator using a high impedance bias flow circuit for

approximately 2 hours and received 75% humidified oxygen. Blood pressure, esophageal pressure, ECG, rectal temperature and end tidal CO_2 and $O2$ were monitored. Several times during the study a droplet of radioactive tagged iron oxide was instilled in the trachea and its movement was recorded by means of a tracheal probe.

Results:

a) The dog was well ventilated throughout the course of the experiment.

b) The animal was ventilated at 5 and 10Hz, full power and I:E ratios of 50:50, 70:30 and 30:70.

c) This was a large animal and suction in the bias flow circuit was not adequate.

d) There was difficulty keeping the dog under anesthesia.

e) Because of these difficulties no tracheal rates were recorded.

3) A dog was anesthetized with surital and paralyzed with curare. The animal was placed on the ventilator using a newly constructed high impedance bias flow circuit for three hours and received 40% humidified oxygen. Blood pressure,

esophageal pressure, ECG, rectal
temperature, and end tidal CO_2 and O2
were continuously monitored. Several
times during the study a droplet of
radioactive tugged iron oxide was
instilled in the trachea and its move-
ment was recorded.

Results:

a) The dog was well ventilated
    throughout the course of the
    experiment.
b) The animal was ventilated at 10Hz,
    full power and I:E ratios of 50:50,
    70:30 and 30:70
c) In all cases mucus moved up the
    trachea

4) A dog was anesthetized with surital and
    placed on the ventilator for 2 hours. A
    high impedance bias flow circuit was
    used and the animal received 40%
    humidified oxygen. Blood pressure,
    esophageal pressure, ECG, rectal
    temperature and end tidal O2 and CO_2
    were monitored. Several times during
    the study a droplet of radioactive
    tagged iron oxide was instilled in the
    trachea and its movement was recorded.

Results:

a) The dog was well ventilated
    throughout the experiment.

b) The animal was ventilated at 5 Hz,
Full power and I:E ratios of 50:50
and 70:30

c) Mucus moved up the trachea.

5) A dog was anesthetized with surital and
placed on the ventilator for 3 hours. A
high impedance bias flow circuit was
used and the animal received 40% ·
humidified oxygen, blood pressure,
esophageal pressure, ECG, rectal
temperature and end tidal $O2$ and CO_2
were monitored. Several times during
the study a droplet of radioactive
tagged iron oxide was instilled in the
trachea and its movement was recorded.

Results:

a) The dog was well ventilated
throughout the experiment.

b) The animal was ventilated at 5 Hz,
Full power and I:E ratios of 50:50,
70:30 and 30:70

c) Mucus moved up the trachea.

6) A dog was anesthetized with surital and
placed on the ventilator for 2 hours. A
high impedance bias flow circuit was
used and the animal received 40%
humidified oxygen, blood pressure,

esophageal pressure, ECG, rectal
temperature and end tidal O_2 and CO_2
were monitored. Several times during
the study, a droplet of radioactive
tagged iron oxide was instilled in the
trachea and its movement was recorded.

Results:

a) The dog was well ventilated
throughout the course of the
experiment.
b) The animal was ventilated at 10 Hz,
Full power and I:E ratios of 70:30
and 25:75.
c) In all cases mucus moved up the
trachea.

Another experimental series was conducted to
determine if premature baboons with Hyaline Membrane
Disease can be supported by the machine.

Eight baboons were delivered by sterile
caesarean section at 137 to 143 days gestational age
and were ventilated by the machine. 5 were 2 hour
short term models and 3 were 24 hour models. The 2
hour models were ventilated at 15 Hz, 33% I and Power
as required (12% to 85%). The 24 hour models were
ventilated at 10 Hz, 33% I and power as required.

All of the animals survived and there were
no malfunctions.

Optimum blood gas values and mean proximal
airway pressures are shown below for the 2 hour models
comparing IPPV and HFV.

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IPPV (Intermittent Positive Pressure Ventilation)

Animal	PaCO$_2$	PaO$_2$ (arterial pressure)	(A alveolar O2	-aO2) arterial O2	MAP
Q	31	213		428	18
R	24	233		417	13
S	38	119		434	16
T	22	198		455	13
U	41	184		445	28
AVG.	31.2	189		436	17.6

HFV (High Frequency Ventilation)

Animal	PaCO$_2$	PaO$_2$		(A-aO2)	MAP
Q	22	215		437	11
R	31	214		427	18
S	18	298		360	16
T	38	248		385	17
U	31	230		411	14
AVG.	28	241		404	15.2

Average arterial blood gases for the 2 hour models comparing
IPPV and HFV ar shown below

	IPPV			HFV		
	PaO_2	$PaCO_2$	pH	PaO_2	$PaCO_2$	pH
Q	127	40	7.09	103	29	7.29
R	97	36	7.25	141	24	7.31
S	92	47	7.04	214	29	7.35
T	140	31	7.32	162	45	7.15
U	115	46	7.16	145	36	7.19
AVG	114	40	7.17	153	33	7.26

Although the invention has been described in
conjunction with the foregoing specific embodiment,
many alternatives, variations and modifications are
intended to fall within the spirit and scope of the
appended claims.

CLAIMS:-

1.   An apparatus for supporting full ventilation of an air breathing animal, comprising:

a source of gas for respirating said animal;

means for supplying a continuous flow of said gas from said source at a flow rate;

means for generating a high frequency, variable frequency, variable period, variable amplitude, pressure wave, which is polar relative to the static airway pressure in said animal, in said continuous flow of gas; and

means for connecting said flow of gas with said high frequency wave to the lungs of an animal to be ventilated.

2.   An apparatus as set forth in Claim 1, wherein said connecting means comprises an endotracheal tube having an outlet opening externally of said animal.

3.   An apparatus as set forth in Claim 1 including means for maintaining an elevated static airway pressure in said animal.

4.   An apparatus as set forth in Claim 1, wherein said generating means comprises a linear motor.

5.   An apparatus as set forth in Claim 4, wherein said generating means further comprises means for driving said linear motor with a square wave signal.

6. An apparatus as set forth in Claim 1, including means for independently varying the duration of said positive portion of said pressure wave and said negative portion of said pressure wave.

7. An apparatus set forth in Claim 1, wherein said connecting means comprises an end external of said patient having an inlet opening for receiving said gas, and an outlet opening for venting gas at said flowrate.

8. An apparatus as set forth in Claim 7 including means connected to said outlet opening for maintaining an elevated static pressure in said connecting means.

9. An apparatus as set forth in Claim 8, wherein said elevated static pressure is less than 100 cm H_2O.

10. An apparatus as set forth in Claim 1, wherein said high frequency is above 3 Hz.

11. An apparatus as set forth in Claim 1, wherein said generating means includes means for automatically switching between two frequencies, periods and amplitudes.

12. An apparatus as set forth in Claim 11, wherein one of said two frequencies is a low frequency for producing a sigh in said animal.

13. An apparatus for supporting full ventilation in an air breathing animal, comprising:

a source of respirating gas;

means for supplying said respirating gas to an airway of an animal; and

means for producing a high frequency, variable period pressure wave in said gas which is polar relative to the static airway pressure in said animal such that said pressure wave has positive and negative amplitude portions relative to said static airway pressure, said wave having a positive sloped portion forcing gas into said airway and a negative sloped portion drawing gas out of said airway.

14.   An apparatus as set forth in Claim 13, wherein said supplying means comprises means for producing a continuous flow of gas and a tube connecting said continuous flow to said airway, said tube having an outlet opening externally of said animal, said pressure maintaining means comprising a valve in said outlet opening.

15.   An apparatus as set forth in Claim 13 including means for independently varying the duration of said positive portion of said pressure wave and said negative portion of said pressure wave.

16.   An apparatus as set forth in Claim 13, wherein said pressure maintaining means produces a static pressure less than 100 cm H_2O.

17.   An apparatus as set forth in Claim 13, wherein said high frequency is greater than 3 Hz.

18. An apparatus as set forth in Claim 13, wherein said pressure wave producing means comprises a linear motor connected to a diaphragm.

19. An apparatus for ventilating an air breathing animal, comprising:

a source of ventilating gas connected to said air breathing animal; and

means for producing a high frequency pressure wave in said gas, said means comprising a diaphragm in contact with said gas, a linear motor having an armature connected to said diaphragm, circuit means including an oscillator producing a high frequency output for driving said linear motor, and means for equalizing the pressure on opposite sides of said diaphragm.

20. An apparatus as set forth in Claim 19, wherein said circuit means includes shaping circuitry for shaping the output of said oscillator into a polar square wave.

21. An apparatus as set forth in Claim 19, wherein said circuit means includes means for switching the frequency of said oscillator automatically between said high frequency and a low frequency.

22. An apparatus as set forth in Claim 19 including means for switching the frequency of said oscillator automatically between said high frequency and a second high frequency.

23. An apparatus as set forth in Claim 19 including a second oscillator for producing a second frequency output, and means

for superimposing said second frequency output on said high fre-

quency output.

24. An apparatus as set forth in Claim 19 including feed-back means in said linear motor for producing a feedback signal indicative of the position of said armature.

25. An apparatus as set forth in Claim 19, wherein said linear motor includes a pressure chamber, said diaphragm being disposed in said pressure chamber, said diaphragm being disposed in said pressure chamber.

26. A method for ventilating an air breathing animal, comprising:

producing a continuous flow of ventilating gas;

supplying said continuous flow of gas to an animal to be ventilated;

generating a high frequency, variable period pressure wave in said flowing gas, said pressure wave being generated with positively and negatively sloped portions to actively force gas into and draw gas out of said animal; and

venting gas at a rate equal to the rate of flow of said gas,

whereby carbon dioxide from said animal and ventilating gas are exchanged and diffused throughout the airway of said animal and said flowing gas in such a manner that sufficient ventilating gas reaches the alveolar sacs of said animal to support full ventilation without spontaneous breathing by said animal or the use of additional ventilating devices, and said vented gas removes carbon dioxide from the animal.

27. A method as set forth in Claim 26, wherein the step of generating a high frequency wave comprises generating said wave at a frequency higher than 3 Hz.

28. A method as set forth in Claim 26 including maintaining the static airway pressure of said animal at an elevated level.

29. A method as set forth in Claim 28, wherein said airway pressure is maintained below 100 cm H_2O.

30. A method as set forth in Claim 29, wherein said mean airway pressure is maintained below 40 cm H_2O.

31. A method as set forth in Claim 28, wherein said elevated static airway pressure is produced by restricting the flow of said vented gas such that an elevated pressure is required to produce a flow rate equivalent to the rate of flow of said ventilating gas.

32. A method as set forth in Claim 26, wherein said step of generating a high frequency pressure wave includes generating said high frequency pressure wave with positive and negative portions relative to the static airway pressure of said animal such that said pressure wave does not substantially alter said mean airway pressure.

33. A method as set forth in Claim 26, wherein said high frequency pressure wave is generated by a linear motor.

34.   A method as set forth in Claim 33, wherein said linear
motor is driven by a polar square wave.

35.   A method as set forth in Claim 32 including the step
of varying the duration of the positive portion and the
negative portion of said pressure wave to vary the
inspiration to expiration ratio of said animal.

36.   A method as set forth in Claim 32 including the step
of varying the peak to peak amplitude of said pressure wave.

37.   A method as set forth in Claim 26 including the step
of generating a second frequency pressure wave superimposed
on said high frequency pressure wave.

38.   A method as set forth in Claim 26 including switching
between said high frequency pressure wave and a second
frequency wave at timed intervals.

39.   A method as set forth in Claim 38 including
generating said second frequency wave at a low frequency
and high amplitude to produce a sigh.

40.   A method as set forth in Claim 26, wherein said
continuous flow is at a rate in the range of 5 liters
per minute.

41.   A method for ventilating an air breathing animal,
comprising:
        supplying a vetilating gas to said animal; and

generating a high frequency, variable period, polar pressure wave in said gas, said polar pressure wave having positive and negative portions relative to the static airway pressure in said animal.

42. A method as set forth in Claim 41 including maintaining said static airway pressure at an elevated pressure for holding the airways open.

43. A method as set forth in Claim 42, wherein said elevated pressure is less than 100 cm H_2O.

44. A method as set forth in Claim 43, wherein said elevated airway pressure is less than 40 cm H_2O.

45. A method as set forth in Claim 41, wherein said inspiration ratio is in the range of 70:30 to 30:70.

46. A motor for producing a polar pressure wave, comprising:

a linear armature;

a coil for producing linear movement in said armature;

signal generation means for producing a polar signal;

circuit means for connecting said polar signal to said coil for producing bidirectional linear movement in said armature;

a pressure chamber;

a diaphragm disposed in communication with said pressure chamber and connected to said linear armature; and

means for equalizing the pressure on opposite sides of said diaphragm.

47. A motor as set forth in Claim 46 including feedback means connected to said armature for producing a signal indicative of the position of said armature.

48. A motor as set forth in Claim 47, wherein said feedback means comprises a light emitting element and a photosensitive element.

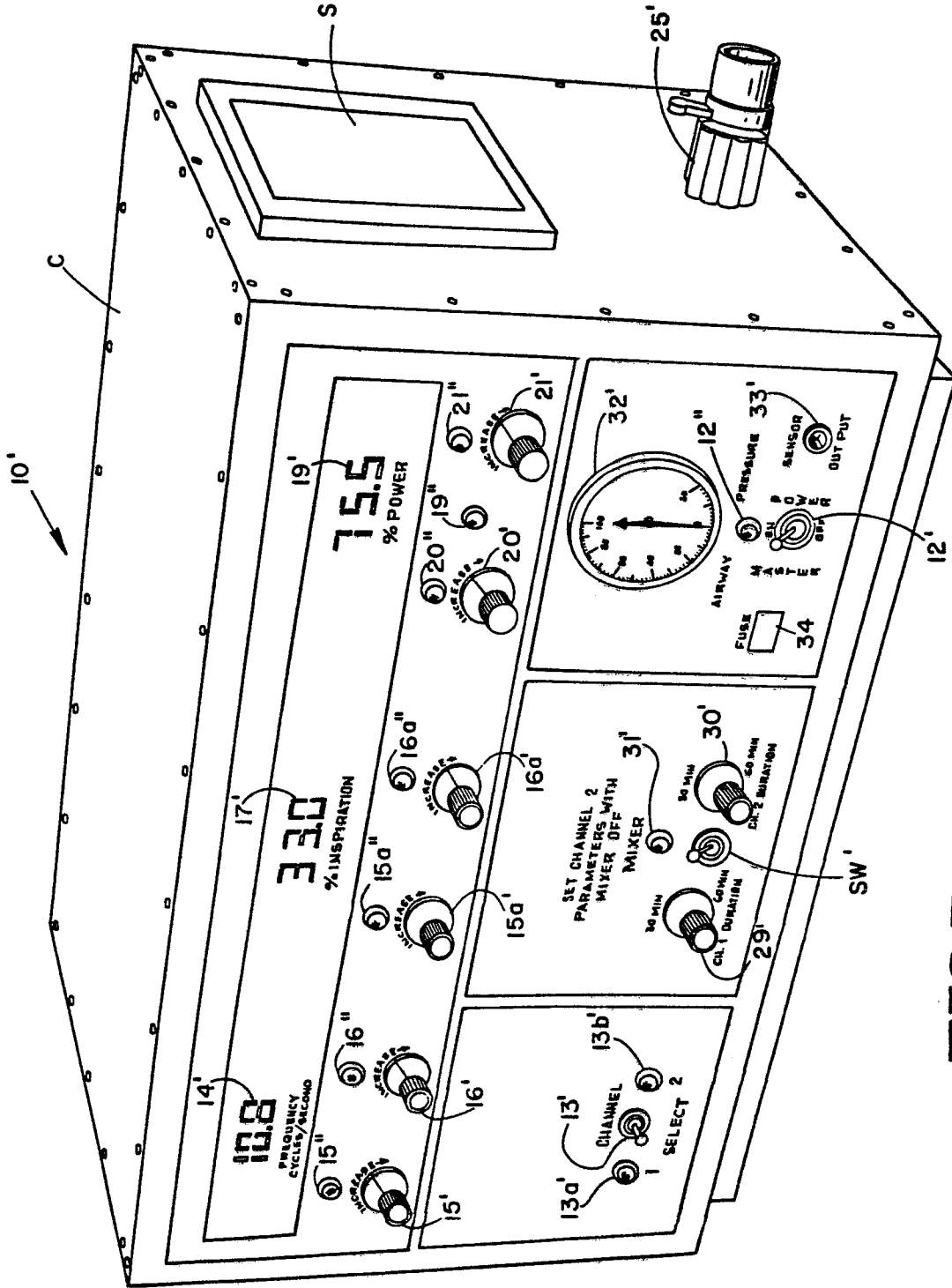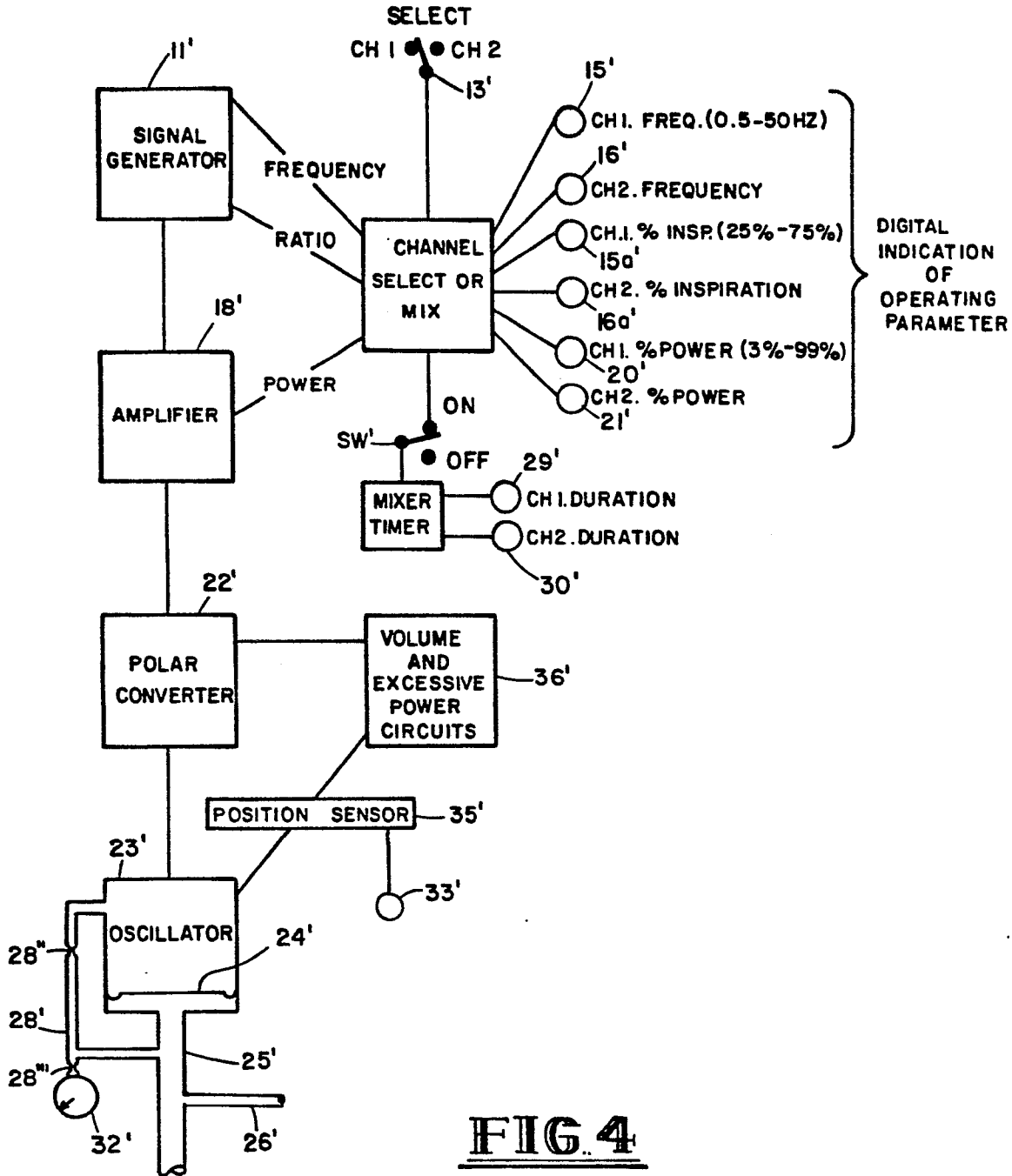49. A motor as set forth in Claim 47, wherein said polar signal is a polar square wave.
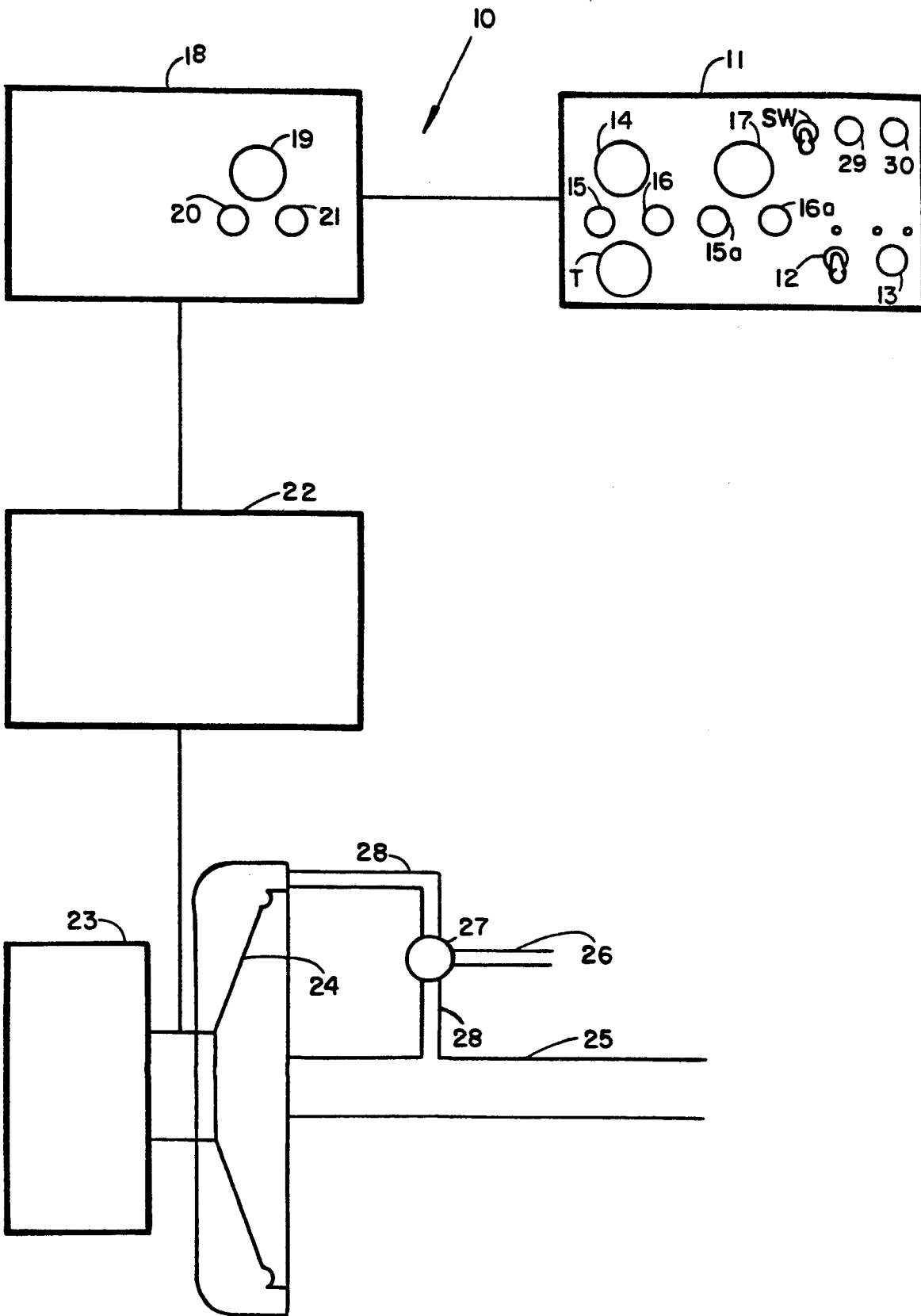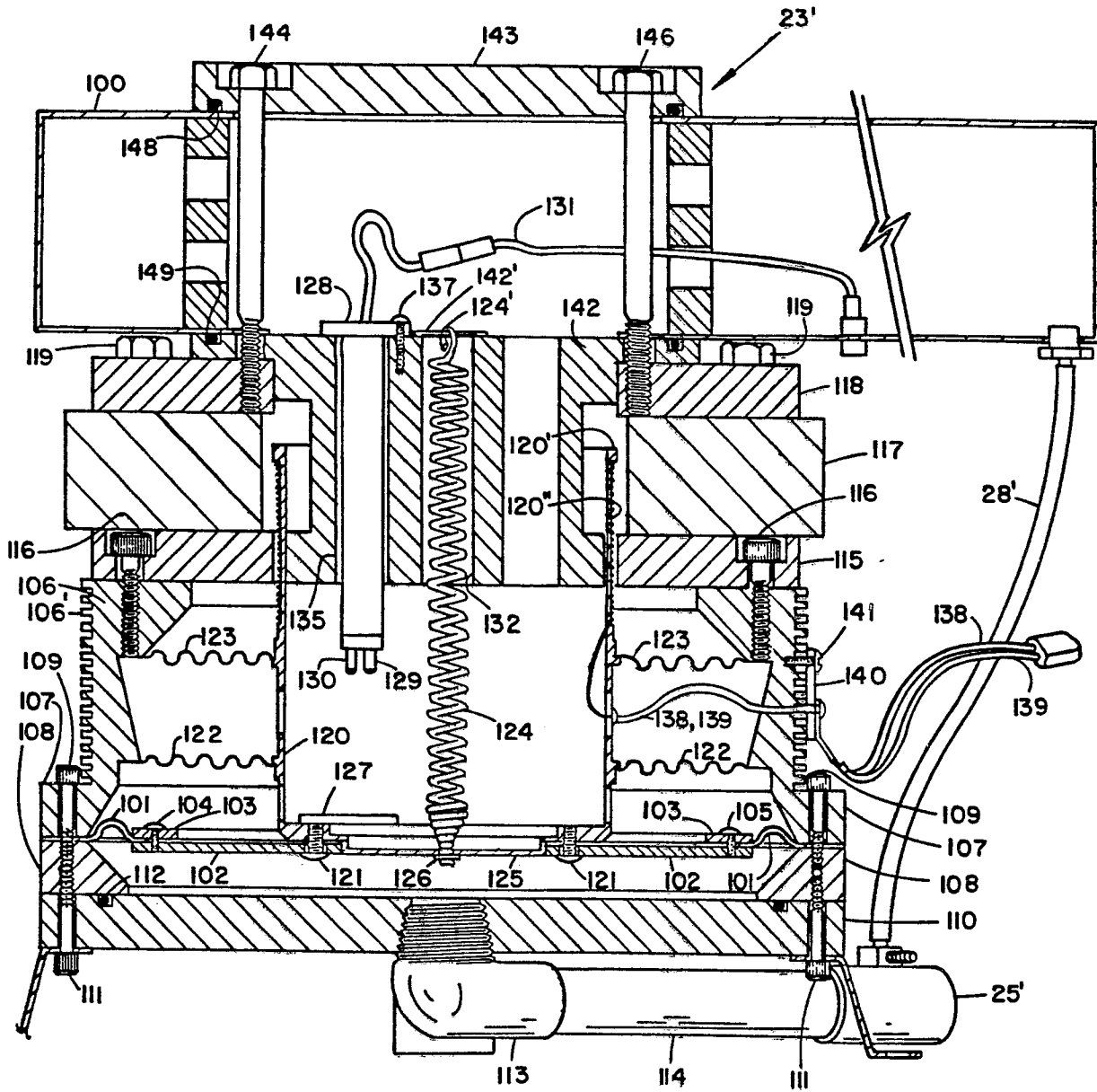
FIG.1

FIG.2

FIG 3
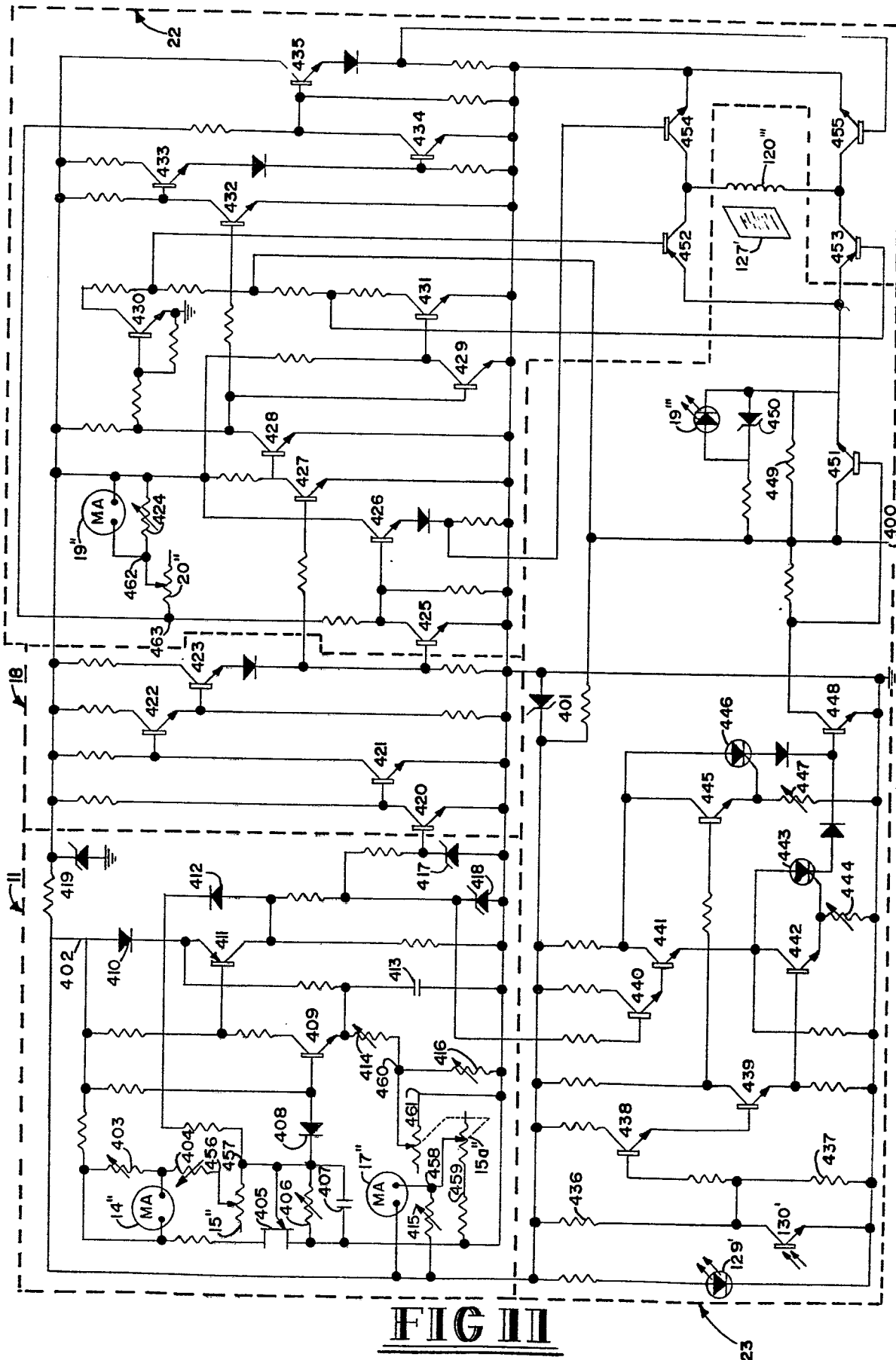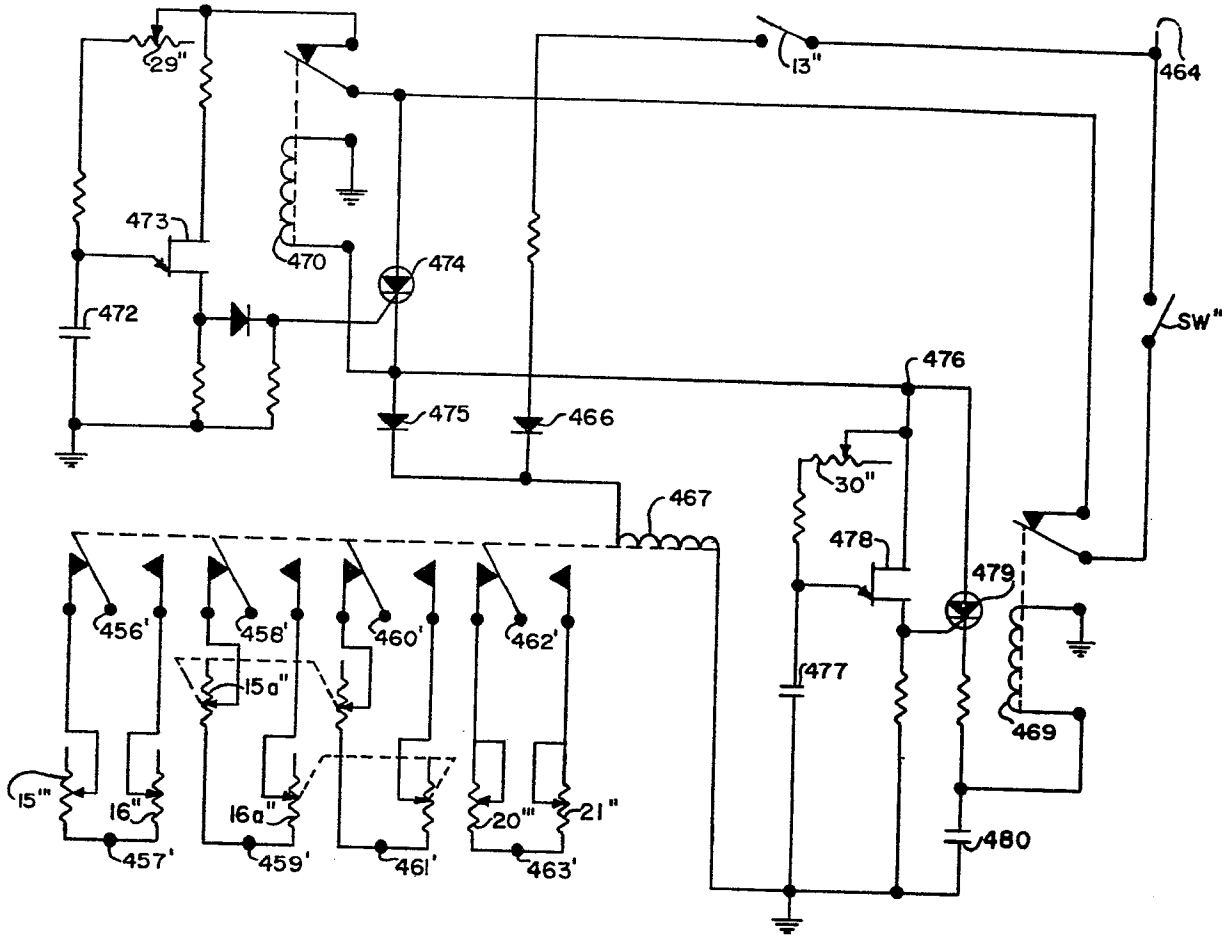
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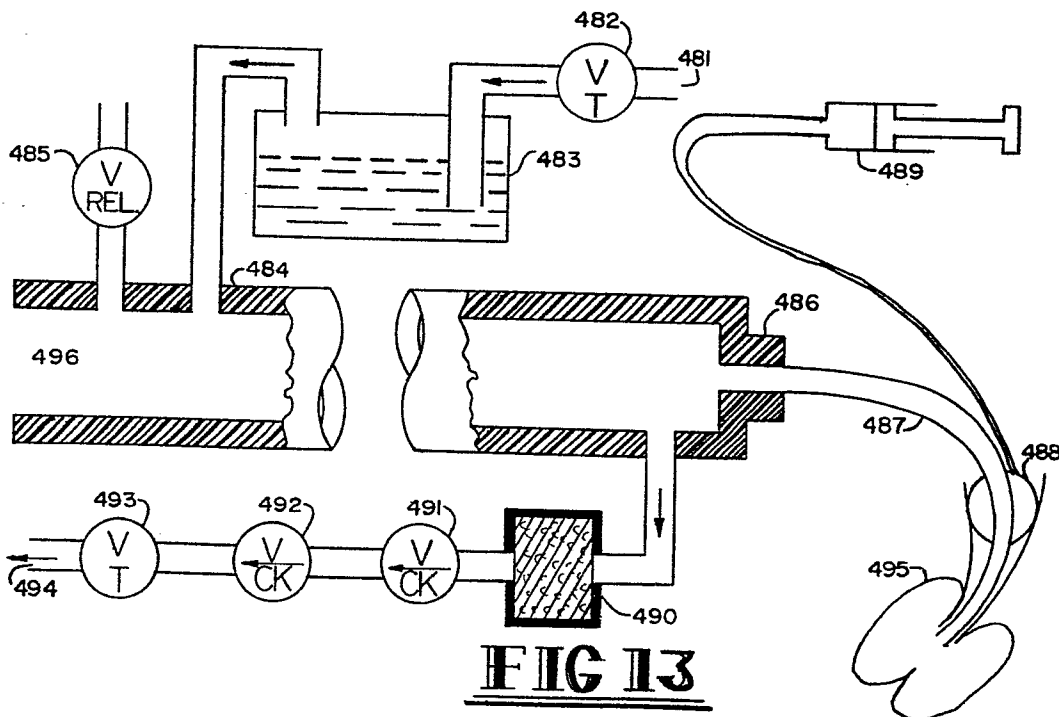
FIG 5
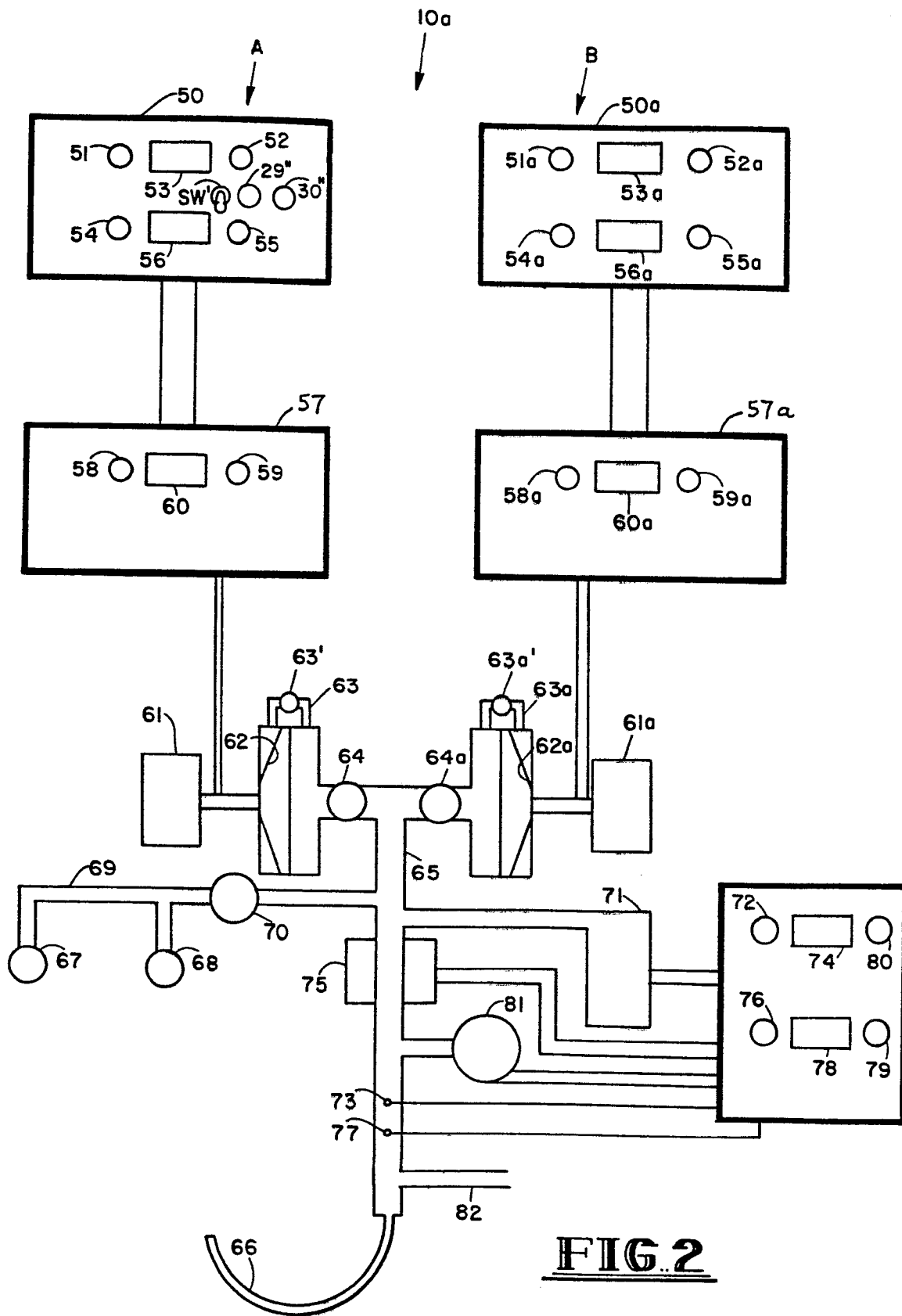
FIG. 6

FIG 7

FIG 9

FIG. 8

FIG 10
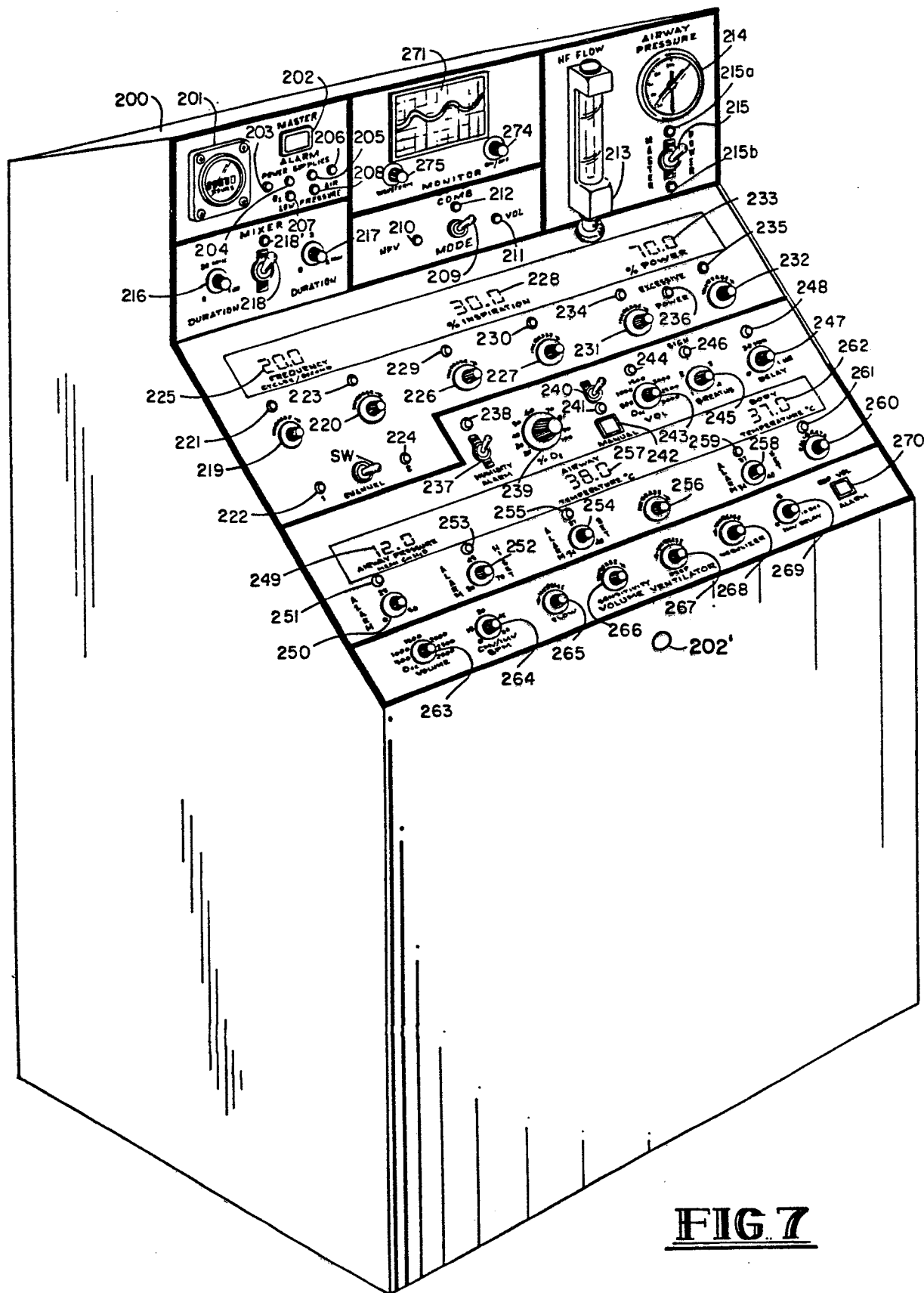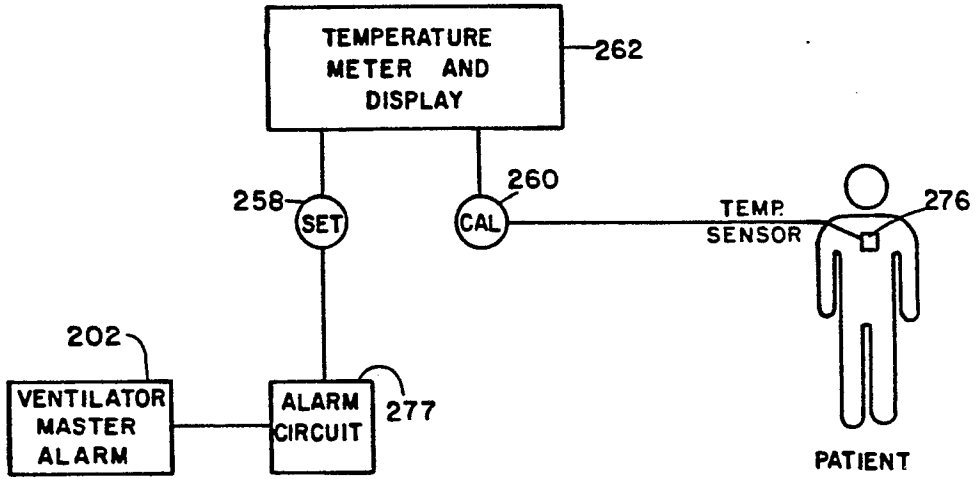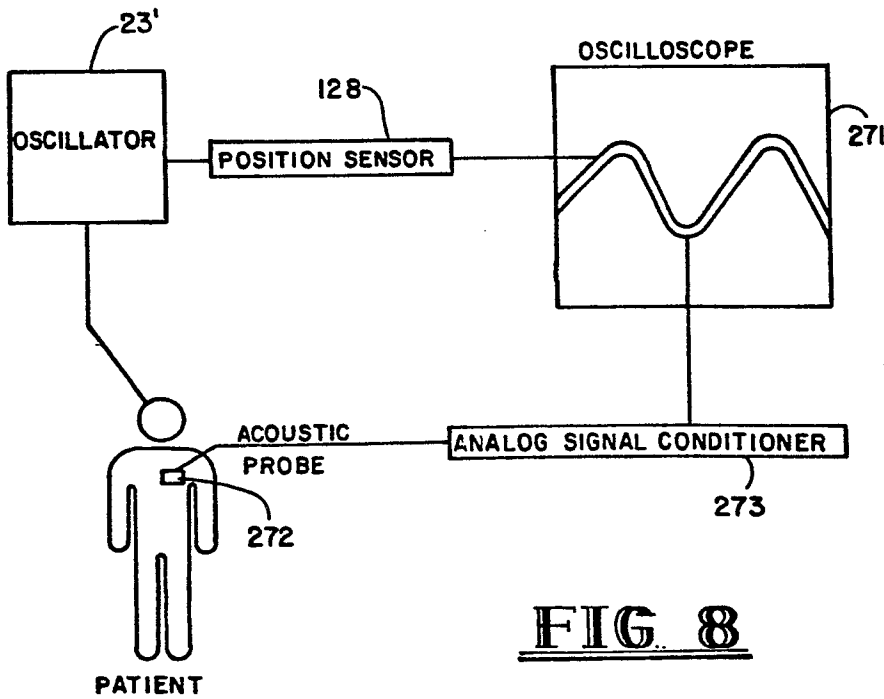
FIG II

FIG 12

FIG 13

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PARTIAL EUROPEAN SEARCH REPORT
which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

EP 84305225.9

	DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (Int. Cl.³)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	EP - A2 - 0 080 155 (BUNNELL LIFE SYSTEMS) * Totality, especially fig. 1; page 4, line 28 - page 6, line 19; page 6, line 32 - page 7, line 31; page 8, line 24 - page 9, line 10; page 10, line 25 - page 13, line 4 * --	1-3,6- 10,13- 17,19	A 61 M 16/00 F 04 B 43/04
D,A	US - A - 4 155 356 (J.G. VENEGAS) * Totality, especially column 5, line 63 - column 10, line 17 * --	1-4,7, 10,13, 14,17- 19,25, 46	TECHNICAL FIELDS SEARCHED (Int. Cl³) A 61 M 16/00
D,A	US - A -2 918 917 (J.H. EMERSON) * Totality, especially column 3, lines 43-67; column 4, lines 23-25 * --	1,3,7, 10,13, 14,17, 19,25	A 61 B 7/00 F 04 B 43/00
D,A	US - A - 4 265 237 (E. SCHWANBOM et al.) * Totality * --	1-3,7, 8,10, 13,14, 17,19	

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.

Claims searched completely: 1-25, 46-49
Claims searched incompletely: —
Claims not searched: 26-45
Reason for the limitation of the search:

in order to Article 52(4)

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
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L: document cited for other reasons

&: member of the same patent family, corresponding document

Place of search	Date of completion of the search	Examiner
VIENNA	20-12-1984	LUDWIG

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EP 84305225.9

	DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	<u>GB - A - 1 553 379</u> (ASSISTANCE TECHN. MED.) * Totality * --	1,4-7, 13-15, 18-20, 25,46	
A	<u>US - A - 3 349 766</u> (D.J. DONOFRIO) * Totality * --	1,2,7, 13,14, 19	
A	<u>US - A - 4 036 221</u> (D. HILLSMAN et al.) * Fig. 1,5,7; column 6, line 1 - column 7, line 15; column 8, line 16 - column 9, line 7; column 10, line 12 - column 12, line 37 * --	1-4,6-8,13-15, 18,19, 24,25, 46,47	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A	<u>US - A - 3 863 082</u> (D.H. GILLOTT et al.) * Totality * ----	1,4,19, 46	

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